A Dissertation on

"COMPARISON OF I-GEL AND LMA FASTRACH AS A CONDUIT FOR BLIND TRACHEAL INTUBATION"

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THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY, CHENNAI, TAMILNADU

APRIL 2017

DECLARATION

I, **Dr. R. ANU ASHEETHA**, Solemnly declare that the dissertation, Titled "**Comparison of I-GEL and LMA FASTRACH as a conduit for blind tracheal intubation"**, is a bonafide work done by me during the period of January 2016 to July 2016 at Government Tirunelveli Medical College and Hospital, Tirunelveli under the expert guidance and supervision of Dr.**A.BALAKRISHNAN,** M.D, Professor and Head, Department Of Anaesthesiology, Government Tirunelveli Medical College, Tirunelveli.

This thesis is submitted to The Tamil Nadu Dr. M.G.R. Medical University in partial fulfilment of the rules and regulations for the M.D. degree examinations in Anaesthesiology to be held in April 2017.

Tiruneveli **Dr. R. ANU ASHEETHA**

Date:

CERTIFICATE

This is to certify that the dissertation entitled "**Comparison of I-GEL and LMA FASTRACH as a conduit for blind tracheal intubation**" is a genuine work done by **Dr. R. ANU ASHEETHA** for the partial fulfilment of the requirements for M.D. (Anaesthesiology) Examination of The TamilNadu Dr. M.G.R. Medical University to be held in April 2017, under my supervision and the guidance of **Dr. BRIDJIT MERLIN**, M.D., D.A., D.N.B., Assistant Professor, Department of Anaesthesiology at Tirunelveli Medical College, Tirunelveli.

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PROTOCOL TITLE: A COMPARATIVE STUDY OF TRACHEAL INTUBATION THROUGH ICEL AND INTUBATING LARYNGEAL MASK AIRWAY

PRINCIPAL INVESTIGATOR: DR.R.ANU ASHEETHA, MBBS.,

DESIGNATION OF PRINCIPAL INVESTIGATOR POST GRADUATE IN ANAESTHESIOLOGY
DEPARTMENT & INSTITUTION: TIRUNELVELI MEDICAL COLLEGE , TIRUNELVELI

Dear , Dr.R.Anu Asheetha, MBBS., The Tirunelveli Medical College Institutional Ethics Committee (TIREC) reviewed and discussed your application during the IEC meeting held on 10.12.15.

THE FOLLOWING DOCUMENTS WERE REVIEWED AND APPROVED

1. TIREC Application Form ☐
2. Study Protocol ☐
3. Department Research Committee Approval ☐
4. Patient Information Document and Consent Form in English and Vernacular Language ☐
5. Investigator's Brochure ☐
6. Proposed Methods for Patient Accrual Proposed ☐
7. Curriculum Vitae of the Principal Investigator ☐
8. Insurance /Compensation Policy ☐
9. Investigator's Agreement with Sponsor ☐
10. Investigator's Undertaking ☐
11. DCGI/DGFT approval ☐
12. Clinical Trial Agreement (CTA) ☐
13. Memorandum of Understanding (MOU)/Material Transfer Agreement (MTA) ☐
14. Clinical Trials Registry-India (CTRI) Registration ☐

THE PROTOCOL IS APPROVED IN ITS PRESENTED FORM ON THE FOLLOWING CONDITIONS

1. The approval is valid for a period of 2 year/s or duration of project whichever is later
2. The date of commencement of study should be informed
3. A written request should be submitted 3weeks before for renewal / extension of the validity
4. An annual status report should be submitted.
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    c. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented.
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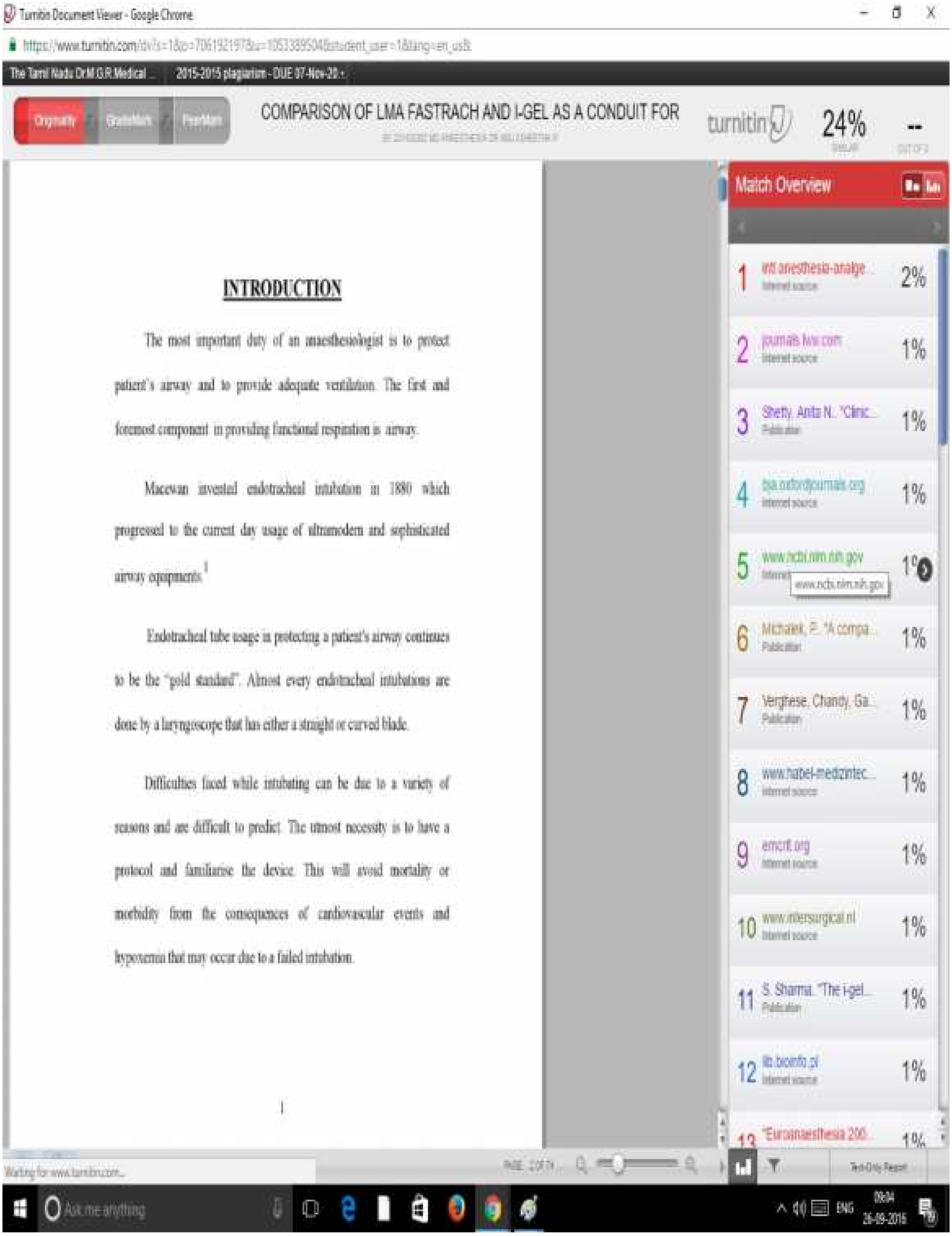

INTRODUCTION

The most important duty of an anaesthesiologist is to protect patient's airway and to provide adequate ventilation. The first and foremost component in providing functional respiration is airway.

Macewan invented endotracheal intubation in 1880 which progressed to the current day usage of ultramodern and sophisticated airway equipments.[1]

Endotracheal tube usage in protecting a patient's airway continues to be the "gold standard". Almost every endotracheal intubations are done by a laryngoscope that has either a straight or curved blade.

Difficulties faced while intubating can be due to a variety of reasons and are difficult to predict. The utmost necessity is to have a protocol and familiarise the device. This will avoid mortality or morbidity from the consequences of cardiovascular events and hypoxemia that may occur due to a failed intubation.

1

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1.	LMA	LARYNGEAL MASK AIRWAY
2.	ILMA	INTUBATING LARYNGEAL MASK AIRWAY
3.	ETT	ENDOTRACHEAL TUBE
4.	CETT	CUFFED ENDOTRACHEAL TUBE
5.	MRI	MAGNETIC RESONANCE IMAGING
6.	mm	MLLIMETRE
7.	ml	MILLILITRE
8.	kg	KILOGRAM
9.	cm	CENTIMETRE
10.	FTST	FASTRACH SILICONE TUBE
11.	PVC	POLY VINYL CHLORIDE
12.	PVCT	POLY VINYL CHLORIDE TRACHEAL TUBE
13.	LAT	LATEX ARMOURED TUBE
14.	AIC	AINTREE INTUBATING CATHETER
15.	IV	INTRAVENOUS
16.	mcg	MICROGRAM
17.	IM	INTRAMUSCULAR
18.	CO_2	CARBON DIOXIDE
19.	ASA PS	AMERICAN STATUS ANAESTHESIOLOGIST PHYSICAL STATUS
20.	I.D	INTERNAL DIAMETER
21.	MAP	MEAN ARTERIAL PRESSURE

INTRODUCTION

The most important duty of an anaesthesiologist is to protect patient’s airway and to provide adequate ventilation. The first and foremost component in providing functional respiration is airway.

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Endotracheal tube usage in protecting a patient's airway continues to be the “gold standard”. Almost every endotracheal intubations are done by a laryngoscope that has either a straight or curved blade.

Difficulties faced while intubating can be due to a variety of reasons and are difficult to predict. The utmost necessity is to have a protocol and familiarise the device. This will avoid mortality or morbidity from the consequences of cardiovascular events and hypoxemia that may occur due to a failed intubation.

The anaesthesiologist should be skilled enough to make decisions at the circumstances of difficult intubations. Factors responsible for difficult intubations are addressed by many innovative inventions which led to the evolution of different and improved techniques. It is wise to use cheap, safe and useful devices best suited for the current day anaesthetic set up.

Inserting a supraglottic device in these circumstances is a clever and a life-saving alternative. Few supraglottic devices facilitate blind endotracheal intubation or a fibreoptic technique. Endotracheal intubation through a classical laryngeal mask airway had been extensively studied and is more time consuming.[3 – 5]

One device commonly used as a conduit for tracheal intubation is the intubating laryngeal mask airway (ILMA).[2] Since 1997 the ILMA prove to be the "gold standard" among the supraglottic devices. In circumstances of difficult intubations ILMA has revealed an enormous success rate for blind or fibreoptic-aided tracheal intubation. [6– 10]

I-GEL , a relatively new and an efficient supraglottic device (Intersurgical Ltd., Wokingham, UK) is used for management of airway. It is synthesised from Styrene Ethylene Butadiene Styrene and is naturally designed in such a way to resemble the peri-laryngeal framework. Miller's classification reports it to be the uncuffed perilaryngeal sealer.[11]

I-GEL and ILMA are compared and analysed because ILMA and I-GEL facilitate tracheal intubation blindly. I-GEL has few added advantages over ILMA: it is cheap, disposable and has an extra port for emptying the gastric contents. Moreover, I-GEL insertion is mostly quick and easy .[12]

Moreover , its large circomference allows passage of a calculated size Fastrach silicone tube or endotracheal tube. It proves to be a life saving alternative to orotracheal intubation in circumstances of difficult intubations as reported in many case reports.[13, 14]

Hence a prospective randomized single blind study was designed to compare the advanced I-GEL, to ILMA as a conduit for blind endotracheal intubation for patients posted for elective procedures under general anaesthesia.

AIM OF THE STUDY

The aim of the study is to compare two supraglottic airway devices: I-GEL and Intubating LMA as a conduit for blind endotracheal intubation in patients undergoing elective procedures under general anaesthesia. We compare the two devices on the following metrics:

1) First attempt success rate for blind endotracheal intubation through the supraglottic airway device.

2) Total time required for the successful blind endotracheal intubation through the supraglottic airway device.

3) Ease of placement of supraglottic airway device

    a) Number of attempts required for the placement of the supraglottic airway device

    b) Time required for the placement of the supraglottic airway device.

I-GEL

The I-GEL airway is a novel and innovative supraglottic airway device, made of a medical grade thermoplastic elastomer, Styrene Ethylene Butadiene Styrene, which is soft, gel-like and transparent. The I-GEL is a truly anatomical device preformed to create a non-inflatable anatomical seal of the pharyngeal, laryngeal and peri-laryngeal structures while avoiding the orpharyngeal trauma that can occur with inflatable supraglottic airway devices.

Figure 1: The I-GEL Device

Advantages of I-GEL includes (a) quicker and easier insertion, (b) minimal compression of perilaryngeal structures, (c) position remains stable and unchanged even after cuff inflation, and (d) latex free, (e) sterile, (f) disposable device.

Vertical stability and the axial strength of I-GEL while inserting it , is provided by the buccal cavity stabiliser. It has an integrated airway channel and a standard gastric port. Insertion of fingers into patient's mouth to establish complete insertion is not needed .[15]

An integrated gastric channel acts as an indicator of regurgitation, allows venting of air from the stomach and helps in the passage of a naso-gastric tube to vent out the gastric contents.

Figure 2: Interior of the I-GEL Device

COMPONENTS OF I-GEL

Non-inflatable soft cuff

The transparent flexible non-inflatable soft cuff fits aptly on the laryngeal inlet, resembling the shape of the individual peri laryngeal structures and adjoining spaces. Each structure is supported by the perilaryngeal seal by covering the laryngeal inlet. The oesophageal opening is separated from the laryngeal inlet by the tip of the device. The vascularity of the perilaryngeal structures and the neurovascular continuity is maintained by the outer cuff shape.

Gastric port

The gastric port runs all along the full length of the I-GEL commencing from proximal opening besides the flat connector wing to the non-inflatable cuff's distal tip. This tip fits genty and correctly onto the proximal opening of oesophagus. This gastric channel helps in the passage of naso gastric tube and venting out the gastric contents

Epiglottic rest

A man-made synthetic epiglottis and a strong bar helps in preventing the down-folding of epiglottis and protects the distal opening of the airway. The epiglottic rest fits at the base of tongue, thus stabilising the device and retaining its position on the proximal oesophageal opening.

Buccal cavity stabiliser

The buccal cavity stabiliser encarves a natural curvature and a unique property to resemble the oropharyngeal curvature. It is naturally concaved and broadened to negotiate its rotational property, thus preventing malposition. It enhances its axial strength to aid insertion.

SIZE SELECTION[15]

I-GEL	MAX SIZE OF CETT	NASOGASTRIC TUBE	WEIGHT
Size 3	6.0 mm	12G	30-60 kg
Size 4	7.0 mm	12G	50-90 kg
Size 5	8.0 mm	14G	> 90 kg

Table 1: Various sizes for the I-GEL

INDICATIONS

1. Securing the airway in circumstances of difficult intubations in management of an anaesthetised patient.
2. In circumstances of difficult intubation, the patient is intubated with an endotracheal tube by a fiberoptic guidance through the device..

3. In circumstances of difficult intubation, blind passage of a gum-elastic bougie can be done gently and the ETT is rail roaded over it.

4. Used by the ambulance team in circumstances of difficult intubations in an emergency setting in an idea to secure and establish a secretion free airway.

CONTRA-INDICATIONS

1. Full stomach patients posted for elective and emergency surgical procedures.

2. Restricted mouth opening in patients with trismus, pharyngeal or perilaryngeal abscess, trauma or mass.

3. Peak airway pressure is not allowed to cross 40cm H_2O.

4. Patients assumed to be with full stomach e.g. pregnancy, GERD, hiatus hernia, sepsis, morbid obesity, or a previous history of upper gastro-intestinal surgery etc.

TECHNIQUE OF INSERTION

The I-GEL is lubricated and is held firmly along the in built bite block and the device is placed in such a way that the cuff outlet is pointing towards the chin of the patient. The patient is positioned in '*sniffing the morning air*' position with extended head and flexed neck. The chin is pressed down gently before inserting I-GEL.

The soft leading tip is introduced into the patient's mouth facing the hard palate. Then I-GEL is glided downwards gently and in a backward direction along the hard palate with a gentle sustained push till a definitive resistance is encountered. I-GEL is connected to the circuit and appropriate position and adequate ventilation is confirmed by the bilateral equal and adequate chest rise, auscultation of breath sounds, capnograph trace showing square waves and no oropharyngeal leak.

Excessive force is not needed during the device insertion. Insertion of fingers into the mouth is not needed.

'Jaw thrust', 'Insertion with deep rotation', or Triple manoeuvre is performed when resistance is encountered. After insertion, the device tip is placed onto the proximal opening of oesophagus and the cuff is placed onto the perilaryngeal structures.

An appropriate size endotracheal tube is lubricated and then inserted through the I-GEL. When the endotracheal tube advances smoothly with no resistance, the endotracheal tube cuff is inflated. The endotracheal tube adaptor is then attached and the endotracheal tube position is confirmed by capnograph.

A stabilising rod is used to remove the I-gel. This is done after removing the 15mm endotracheal tube adaptor and grasping the endotracheal tube with fingers. The adaptor is reattached to the endotracheal tube, and after resuming the ventilation, the endotracheal tube position is reconfirmed by capnograph. After confirming the endotracheal tube position, the tube is secured.

INTUBATING LMA

The classic Laryngeal Mask Airway (LMA) acts both as a ventilatory device and as a tool to blind/fibre-optic-guided tracheal intubation.

Dr. A.I.J. Brain investigated on fibre optic which revealed the LMA's advantage as a conduit for endotracheal intubation on his innovations in developing LMA in 1983 .[16]

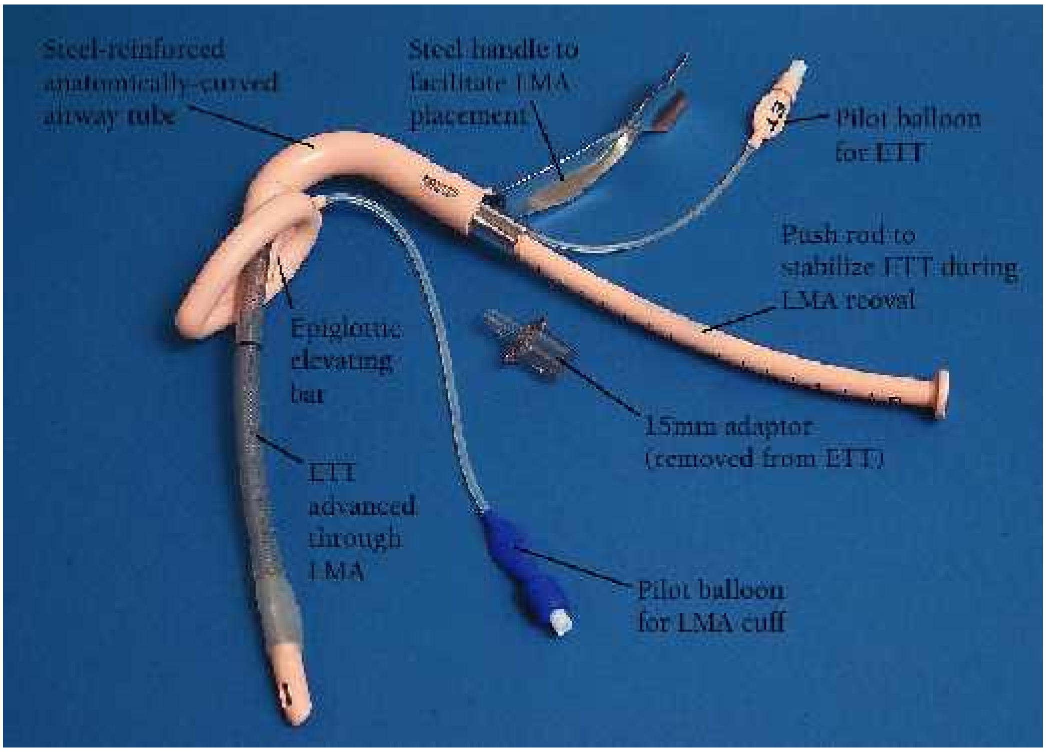


Figure 3: The ILMA Device

In the event of anaesthesiologists' demands for an instrument that has the similar ventilating properties as the classic LMA and also serve as a easier guide for intubation, he invented the Intubating Laryngeal Mask Airway (ILMA; LMA of North America, San Diego, CA) in 1997. This device has better intubating properties than LMA and avoids head and neck manipulation and insertion of fingers inside the mouth during placement. [2]

The device has many features that differentiates it from the classic laryngeal mask airway device. The intubating laryngeal mask airway consists of a naturally curved, rigid stainless steel tube wth an internal diameter of 13 mm which is attached firmly at its lower end to a malleable mask that fits over the larynx.

The shaft angle was carefully laid out using measurements from sagittal MRI images, to fit onto the oropharyngeal space with the neutrally positioned head and neck.

The proximal metal shaft acts as a universal 15 mm connector for the anaesthesia circuit, and a firm directing handle helps to insert the device, avoiding insertion of fingers into the mouth and to stabilize the device while intubating.

Additionally , the twin ridges at the aperture of the classic LMA is substituted in ILMA by a single, flexible epiglottic elevating ridge that lifts epiglottis away and allows for gentle and unobstructed passage of the endotracheal tube as it comes out from the lower end of the ILMA's metal shaft.

This metal shaft admits a flexible, reinforced endo-tracheal tube (ETT) specifically manufactured for this laryngeal mask. The device comes in three sizes for adults (3, 4, and 5), all of which can admit a range of ETT sizes, up to the internal diameter of 8.0mm.

Additionally, the metal shaft is shorter than the LMA Classic, avoiding the need for lengthier endotracheal tubes in patients with long neck.

SIZE SELECTION[17]

ILMA size	Patients' weight	Cuff volume	ETT size
3	30-50 kg	20 ml	6
4	50-70 Kg	30 ml	7
5	70-100 Kg	40 ml	8

Table 2: Various sizes for the ILMA device

INSERTION TECHNIQUE

The patient's head and neck is positioned neutrally and the device is inserted[2] by adopting a single-handed operator technique. The lubricated tip of the deflated mask is positioned behind the upper incisors and the device is glided gently in a downward and backward direction facing the hard palate with a sustained and gentle push to place it in the hypopharynx. Inflation of the cuff is done by injecting air into it (20 ml- size 3; 30 ml- size 4).[18]

ILMA is then connected to the circuit, and correct position and efficient ventilation were confirmed by bilaterally equal and adequate chest rise , auscultation of bilateral air entry, a capnograph trace with square wave, and no oropharyngeal leak.

The Endotracheal tube

The tracheal tube recommended for use with the LMA-Fastrach is a silicone, wire-reinforced, cuffed tube with a tapered patient end and a blunt tip. This tube is flexible, which allows easy negotiation around the anatomical curves of the airway. It has a high pressure, low volume cuff that decreases resistance during intubation and makes cuff perforation less likely, as the tube passes through the ILMA. The shape helps in maintaining the curvature that it attains during its passage through the shaft of the ILMA.[6] It is reusable and costly.

The fastrach silicone reinforced endotracheal tube (8.0mm in males and 7.0mm in females) made for direct intubation into the ILMA is passed. A transverse mark on the endotracheal tube (15 cm) depicts the point at which it is about to come out from the epiglottic elevator.

The endotracheal tube has a line longitudinally, oriented in a direction to face the patient's nose superiorly. Correct orientation of the longitudinal line forces the endotracheal tube to leave the ILMA at an angle that easily guides its passage into the trachea.

The endotracheal tube also has a circumferential line at a distance from the distal tip of the endotracheal tube that is equal to the length of the ILMA from the proximal to the distal port.

ILMA engorges a circumferential line advancing in to the proximal port, and at this junction the ETT tip will touch the epiglottic elevator bar. This epiglottic elevator bar lifts the epiglottis thus preventing it from obstructing the glottis.

After confirming endotracheal intubation, the ILMA is taken out after deflating the cuff. and connector is removed.

The ILMA is taken out while keeping the endotracheal tube in situ by the tube stabilizer and the endotracheal tube is grasped with fingers when it is visible or palpable. The endotracheal tube connector is reattached and ventilation is resumed and the endotracheal tube position is reconfirmed by capnograph.

If resistance is encounterd, the tube is withdrawn one cm beyond the epiglottis elevator . The following manoeuvres[2] were used:

1. ***Extension manoeuvre***

   The handle is pulled back towards the intubator.

2. ***Up-down manoeuvre***

   ILMA is withdrawn by 5cm and then reinserted.

3. ***Optimization manoeuvre***

   Patient is manually ventilated and the position is adjusted till achieving an optimal seal .

4. ***Head–neck manoeuvre***

   Neck flexion and extension of the head (not attempted in anticipated cervical spine pathology)

5. ***Chandy manoeuvre***

   The ILMA is lifted slightly away from the posterior pharyngeal wall.

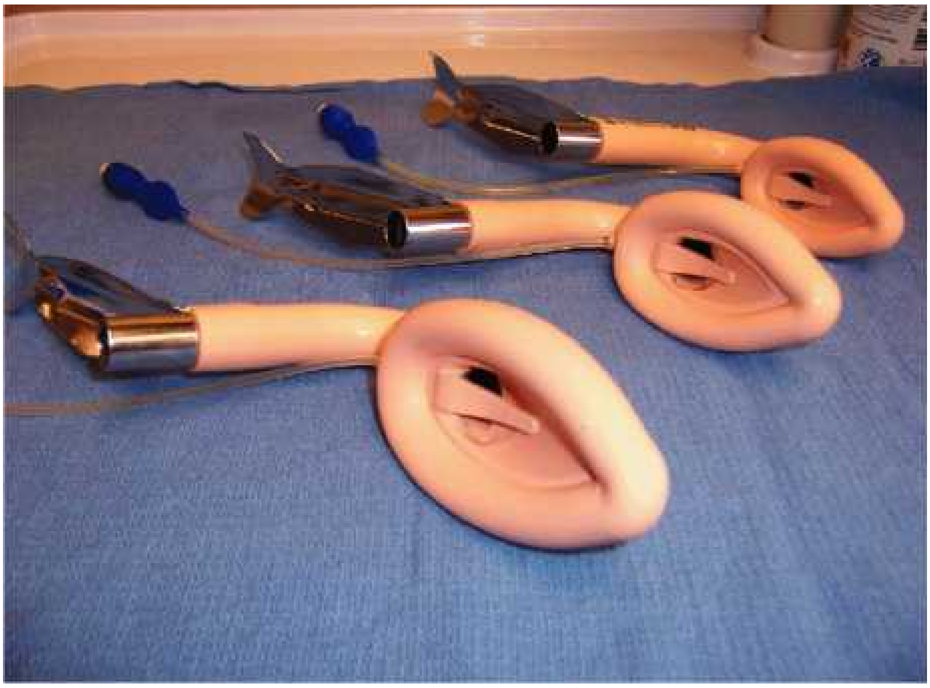


Figure 4: The ILMA Device

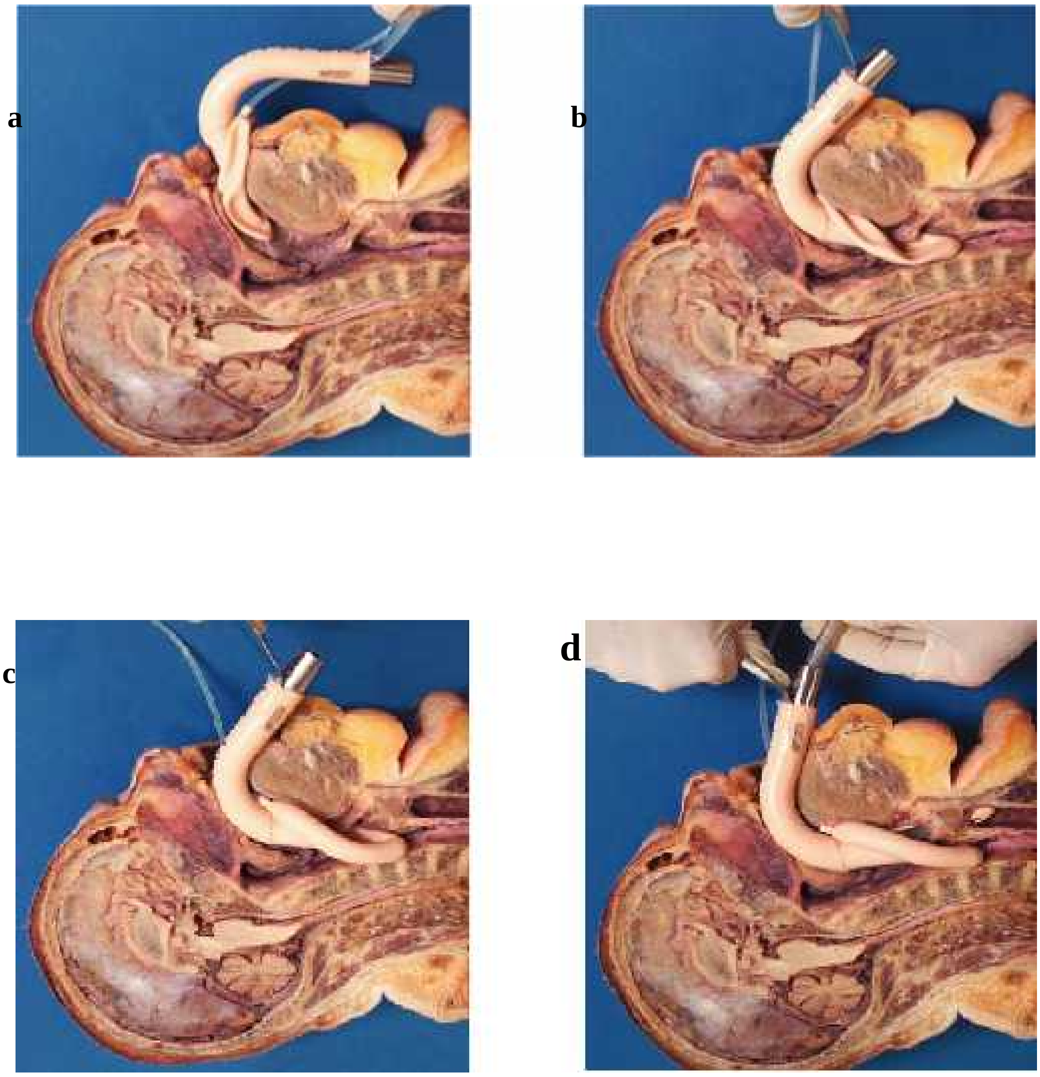


Figure 5: Insertion of the ILMA device and Endotracheal Intubation

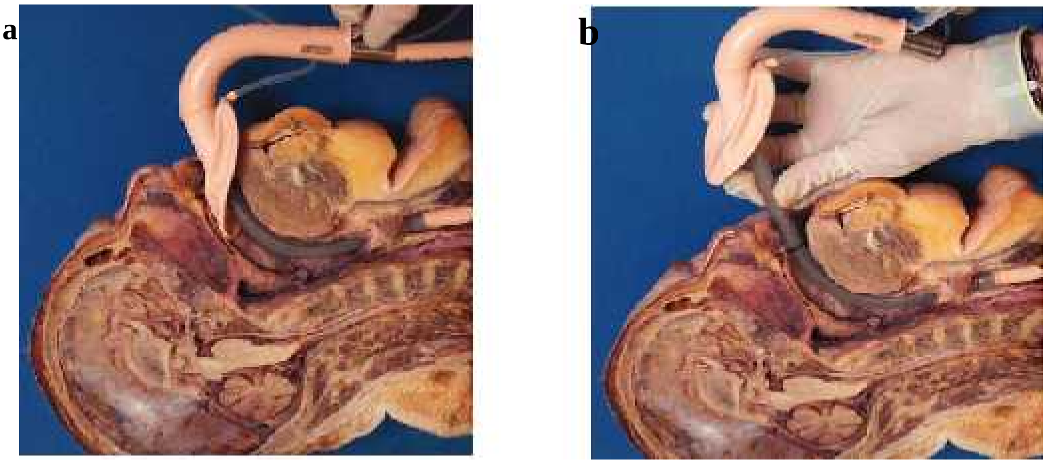


Figure 6: Removal of the ILMA Device with tube in situ

THE CHANDY MANOEUVRE

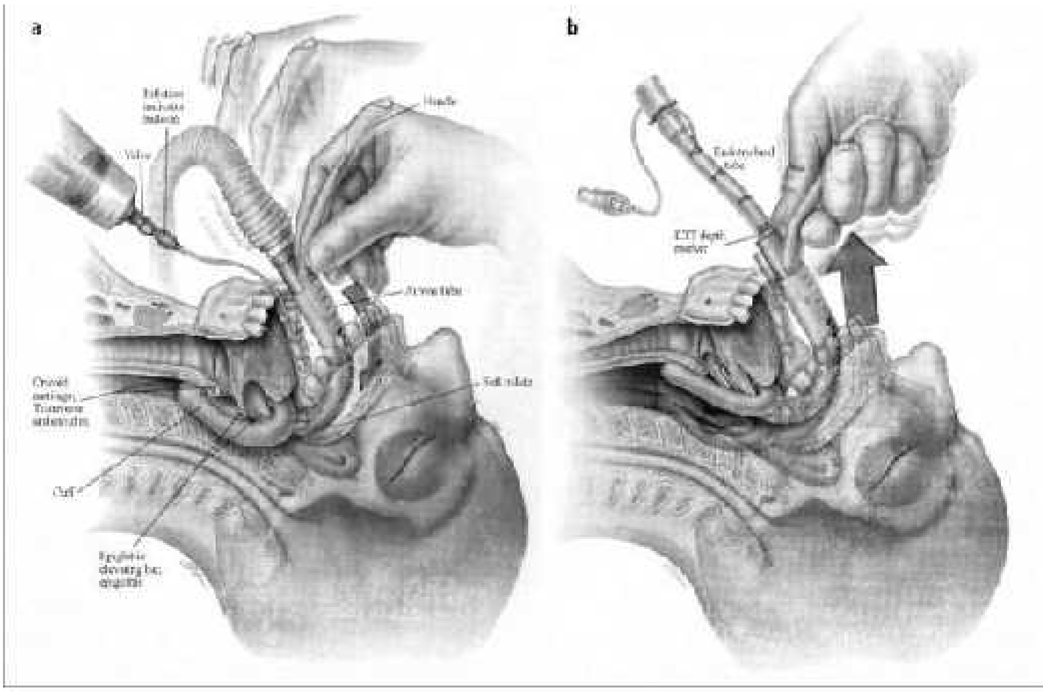


Figure 7: The Chandy manoeuvre

Dr. Chandy Verghese invented a manoeuvre which remarkably improves the efficiency of ILMA. It incorporates two manoeuvres, which are performed sequentially, that improves ventilation of lung and ILMA aided tracheal intubation.

1. The first step of the Chandy manoeuvre, important for achieving adequate ventilation, is rotating the ILMA gently in the sagittal plane using the metal handle until the least resistance to bag ventilation is obtained, while observing the tidal volume delivered to the patient and the tracings in the capnography (if ventilation is

controlled manually). This helps to align the internal aperture of the device with the glottic opening. However, if the patient is breathing spontaneously, an airway whistle (e.g., Patil intubation guide [Anesthesia Associates, San Marcos, CA]) can be attached to the proximal portion of the ILMA to optimize ventilation through it. Maximal whistling indicates optimal positioning of the ILMA.

2. The second part of the Chandy manoeuvre is performed just before blind intubation and consists of using the metal handle to lift slightly (but not tilted) the ILMA away from the posterior pharyngeal wall. This facilitates the smooth passage of the endotracheal tube into the trachea. This prevents the endotracheal tube from colliding with the arytenoids and facilitates the smooth passage of the endotracheal tube into the trachea.[16]

CONVENTIONAL PVC TUBES

The FASTRACH LMA has a wire-reinforced silicone tube (FTST) deviced for blind endotracheal intubation into the intubating LMA (ILMA). It can be reused but costly.

The conventional endotracheal tube made of PVC polyvinyl chloride is rigid and comes out from the ILMA with its lower end pointing too much to the anterior to make its entry into the glottis.[9]

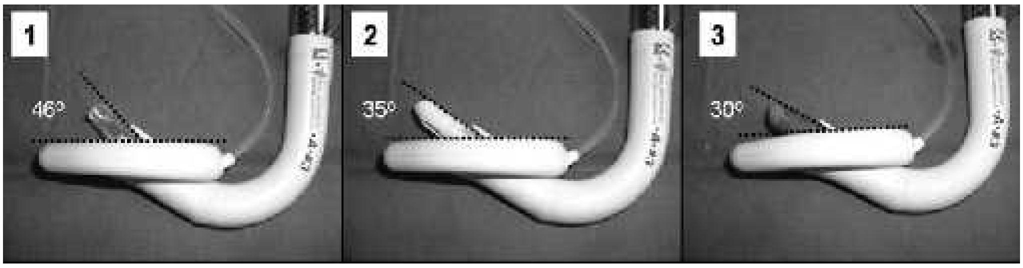
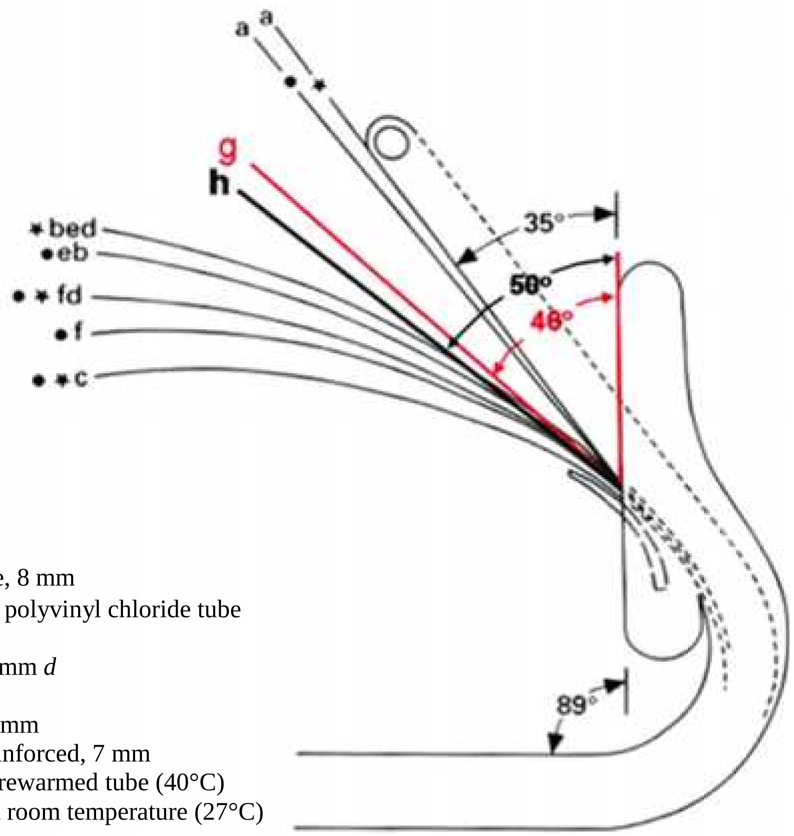


Figure 8: Comparison of emerging angle of FTST, PVC and LAT tubes

Blind endotracheal intubations can be done through the ILMA efficiently by using conventional PVC tubes.

The (PVCT) Rusch PVC endotracheal tube is meant for single use and is much less expensive. Warming a plastic tube will result in success and complication rates similar to that of the tube from the LMA-Fastrach manufacturer.[19]



a = straight silicone tube, 8 mm
b = curved Euromedical polyvinyl chloride tube (PVC), 8 mm
c = Rusch red rubber, 8 mm *d*
= Portex PVC, 8 mm
e = Mallinkrodt PVC, 8 mm
f = Mallinkrodt PVC reinforced, 7 mm
g = Rusch PVC 7-mm prewarmed tube (40°C)
h = Rusch PVC 7 mm at room temperature (27°C)

Figure 9: Effect of tracheal tube curvature for different tubes at 25°C (•) and 37°C (★) when passed through the intubating laryngeal mask airway.

While using the curved PVC tracheal tube, it may be helpful to orient the curve opposite the ILMA curve.[9, 20] Whatever the tracheal tube is used, it is essential that it is possible to remove the connector.[21] It is important to lubricate the tracheal tube well and pass it through the ILMA several times before use.[22]

The PVC tracheal tube is inserted with its anatomical curve along the ILMA curvature and also in the reverse direction. As a result, the angle at which the tip of the tracheal tube emerged from the intubating LMA is 47° or 20°, respectively.

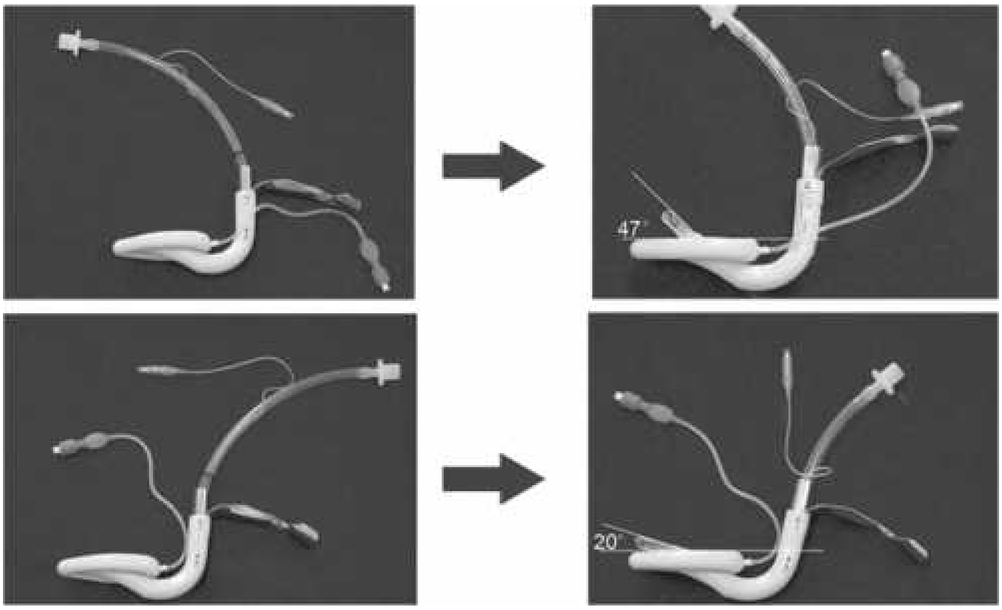


Figure 10: Comparison of emerging angle with orientation of the tracheal tube

REVIEW OF LITERATURE

P. Michaleka et. al. [24] (Resuscitation 2010; 81: 74–77)

The success rate of blind intubation by using a gum-elastic bougie, an Aintree intubating catheter (AIC) and specific tracheal tube was evaluated by Michaleka et al. He also investigated and reported about the fibreoptic scope aided intubation through the intubating laryngeal mask airway and the I-GEL supraglottic airway on three different manikins.

Each method was attempted on each of the three manikins by 25 anaesthetists. Fibre-optic guided technique proved to be more successful than blind techniques ($P < 0.0001$) . No significant difference was noted in fiberoptic techniques with both devices($p>0.05$). ILMA group proved to be successful comparatively to the I-GEL group in case of blind techniques ($P<0.0001$) . Blind intubations are more safer in ILMA and fiberoptic intubations are safer in both ILMA and I-GEL

Dr. Neerja Bharti, Dr. Asit Kumar Naik[25] (Indian J Anaesthesia - 2006; 50(3): 205-208)

Dr. Bharti and Dr. Naik compared the ease of insertion and haemo-dynamic effects following tracheal intubation through intubating laryngeal mask airway (ILMA). Eighty adult patients undergoing elective surgery were randomly allocated into two equal-sized groups.

Tracheal intubation was performed using either intubating laryngeal mask airway or Macintosh laryngoscope. Time to intubation was comparatively longer in ILMA group than laryngoscopy group. The overall intubation success rate was comparable among the groups. Haemodynamic changes were comparatively less in ILMA group than laryngoscope group and were significant. Their results suggested that ILMA offers advantage over laryngoscope in minimizing the haemodynamic effects to intubation. Therefore, it can be used as a suitable alternative to laryngoscopy for tracheal intubation.

Pankaj Kundra, Sujata N, Ravishankar M.[19] (Anesth Analg 2005;100:284–8)

They evaluated the success rate of blind tracheal intubation through the ILMA by using the Fastrach™ silicone wire-reinforced tube (FTST), the Rusch polyvinyl chloride tube (PVCT), and the Rusch latex armoured tube (LAT). 3 Groups with 50 patients as a total of 150 patients were selected. The 3 groups were FTST, pre-warmed PVCT, and LAT. PVCT and FTST were comparatively successful in intubating than with the LAT. First attempt tracheal intubations with the PVCT and FTST (86%) was more easier and quicker than with LAT (52%) ($P<0.05$). LAT group experienced more oesophageal placement compared to the other two groups The authors concluded that a pre-warmed PVCT can be used as successfully as the FTST for blind tracheal intubation through the ILMA, whereas the LAT was associated with more frequent failure and oesophageal intubation.

Hwan S. Joo and D. Keith Rose,[9] (Anesth Analg 1999; 88: 662–6)

They compared the blind and the fibre-optic tracheal intubation using the intubating laryngeal mask airway (ILMA). A standard inhaled anaesthesia induction protocol was deviced. Fibre optic aided tracheal intubations through ILMA (ILMA-FOB) and blind intubations through ILMA (ILMA-Blind) was compared with the group of direct laryngoscopy (laryngoscopy group). Three groups had equal success rates in terms of tracheal intubations. ILMA-FOB group experience a longer total intubation time (77 s versus 48.5 s for laryngoscopy and 53.5 s for ILMA-Blind). They concluded that ILMA is more efficient as a primitive tool for oxygenation and ventilaton. Blind and fiberoptic aided intubations using ILMA acts as an excellent adjunct in difficult intubating conditions

Tao Zhu, MD et al.[23] (Anaesthesia Analgesia 2007; 104: 213-214)

Usage of Mallinckrodt Poly vinyl chloride endotracheal tubes into ILMA was described by Dr. Zhu. He explained about the non intuitive

180 degree angulation to avoid excessive force proved to be a great idea for successful placement. These findings were already reported by Dr.Joo. and Rose. Pre warming the tube reduced the angulation to 20 and 40 degree which made the tube more flexible and eliminated the need for excessive force on the tube.

Ryu Komatsu et al.[26] (Br. J. Anaesth *2004; 93 (5): 655-659)*

They reported the successful usage of ILMA for intubations in patients using rigid cervical collar. They compared two group of patients with each group containing 50 patients. First group consisted of cervical spine patients with Philadelphia collar and second group consisted of general surgery patients. Blind intubations were performed. Both groups had similar findings in relation to total time required for intubation, number of intubation attempts, overall intubation success rate, or the incidence of complications. ILMA proves to be an excellent tool in intubating patients with cervical collar without fiberoptic technique in emergency situations.

A.N.Shetty et. al.[27] (The Internet Journal of Anesthesiology 2006; 10(2))

Blind endotracheal intubation were attempted through ILMA in 75 patients. Though 32% patients had restricted and nil neck movements, ILMA was inserted successfully in 76% and 20% patients in first attempt and second attempt respectively. There was no remarkable change in haemodynamic stability. Hence ILMA acts as a life saving device in circumstances of difficult intubation and also for patients with cervical spine pathology .

Theiler, Lorenz G. et. al.[28] (Anesthesiology 2009; 111 (1): 55-62)

LMA Supreme and I-GEL was compared in this randomized controlled trial . This was done in a difficult airway scenario such as usage of extrication collar The clinical performance of both the devices were same. I-GEL stands ahead by causing less down folding of epiglottis and finer fibre optic view. The main disadvantage is its longer insertion time. Both devices proved successful for intubating patients with limited neck movements.

Pavel Michalek, MD, PhD, et al.[14] (Anesth Analg 2008; 106: 1501–4)

They studied about the successful fibre-optic-guided tracheal intubation through “I-GEL” airway in two elderly agitated patients posted for complex dental treatment under general anaesthesia. Both the patients had learning difficulty, chromosomal aberrations and anticipated dfficult airway.

Airway was well secured and adequate oxygenation and ventilation was established. Fibre optic view of the laryngeal inlet was immediately attained even in the first attempt and tracheal tube was easily inserted without complications.

Gatward JJ.et.al [29] (Anaesthesia 2008; 63(10): 1124-30)

They conducted the study on 100 people posted for elective surgeries. I-GEL is used as an adjunct for intubation in this study. 86 patients, 11 patients, and 3 patients were intubated successfully in 1st , 2nd and 3rd attempts successfully. Median insertion time was 15 s. 87% patients had clear fibre optic view of the glottis through the device. Thus I-GEL was designated to be a reliable airway tool.

Sharma S, Rogers R, Popat M.[13](Anaesthesia 2007; 62: 412-423)

A teenage male patient was scheduled for closure of a colostomy. A size 4 IGEL airway was placed and ventilation was satisfactory. After confirmation of a good view of the vocal cords with a 4.1-mm adult fibreoscope, a size 6.5 mm cuffed tracheal tube was successfully passed through the stem of the IGEL blindly into the trachea at the first attempt. The IGEL was left in place until extubation.

L. de Lloyd et.al.[30] (Anaesthesia, 2010; 65: 36–43)

IGEL and classic laryngeal mask airway was compared. Their efficiency as an adjunct in fiberoptic guide intubations were proved in manikin. They arrived at the conclusion of using as a more preferable option for fiberoptic guided tracheal intubations

R. M. Levitan 12(Anaesthesia 2005; 60: 1022–1026)

They studied the positioning and mechanics of IGEL in 65 non-embalmed cadavers with 73 endoscopies, 16 neck dissections, and six neck radiographs. A full view of the glottis (percentage of glottic opening score 100%) occurred in 44/73 insertions, whereas only 3/73 insertions had epiglottis-only views. Including the eight repeat insertions with a different size, a glottic opening score of > 50% was obtained in all 65 cadavers. The mean percentage of glottic opening score for the 73 insertions was 82%. In each of the neck dissections and radiographs, the bowl of the device covered the laryngeal inlet. They found that the I-GEL effectively conformed to the perilaryngeal anatomy despite the lack of an inflatable cuff and consistently achieved proper positioning for supraglottic ventilation.

MATERIALS AND METHODS

STUDY DESIGN

This study was a single blind, randomized, prospective comparative study conducted in Government Tirunelveli Medical College and Hospital, Tirunelveli

STUDY SETTING AND POPULATION:

The Institutional Ethical committee approval was obtained before commencement of the study. Written informed consent was obtained from all the patients. Eighty adult patients of ASA Physical status 1& 2 of either sex undergoing elective surgical procedures under general anaesthesia were enrolled in the study.

The study was conducted at the General Surgery theatre complex, Tirunelveli Medical College and Hospital, Tirunelveli. The study was conducted from January 2016 to July 2016. The supraglottic airway device insertion and blind tracheal intubation was done by the author.

PATIENT SELECTION

Inclusion criteria:

- Age 16 to 60 years
- Both sexes
- Weight 40-70 kg.
- Mallampatti 3 & 4
- ASA physical status 1-2
- Patients undergoing elective surgery under general anaesthesia, requiring endotracheal intubation

Exclusion Criteria

- Patients with limited mouth opening (less than 2 cm)
- Mallampati 1 and 2
- Patients at increased risk of aspiration, or having a history of symptomatic gastro-esophageal reflux or hiatus hernia.
- Symptoms related to laryngo-pharyngeal anomaly.
- Musculoskeletal abnormalities affecting the cervical vertebrae.

MATERIALS:

- Intubating Laryngeal mask airway (ILMA)
- I-GEL
- Endo-tracheal tube
- IV cannulae,
- Monitors
- Drugs for general anaesthesia

STUDY METHOD:

After obtaining ethical committee approval, two groups were assigned and patients were allocated to the group after randomisation using a closed envelope method with already assigned numbers and then single-blinded.

- Group A: I-GEL for airway management
- Group B: ILMA for airway management

Patients were advised for preoperative overnight fasting for 8 hours. They were given aspiration prophylaxis with Tab Ranitidine 150 mg and Tab Metoclopramide 10 mg on the night before surgery and Inj. Glycopyrrolate 5mcg/kg im, one hour before induction.

Standard monitoring was applied before induction and included ECG, pulse oximeter, capnography and Non-invasive Blood pressure monitor.

Intravenous access was obtained with 18G peripheral venous cannula in the forearm. The patient was placed in supine position with the patient's head on a pillow of 10cms height.

Pre-oxygenation was done for 3 minutes with 100% oxygen. All patients were given Inj. Midazolam 0.02mg/kg iv, Inj. Fentanyl 2 mcg/kg iv. Anaesthesia was induced with Inj. Propofol 2mg/kg iv and Inj Atracurium 0.5 mg /kg iv. The patients' lungs were manually ventilated by face mask with 2% Sevoflurane in oxygen for 3 minutes. An appropriate size supraglottic airway device was then inserted by the author.

Group A (I-GEL)

The patient was positioned in the 'sniffing the morning air' position with extension of head and flexion of neck. Gentle downward pressure over the chin is made before inserting the I-GEL.

The lubricated I-GEL was firmly grasped along the integral bite block and the leading soft tip was introduced into the mouth of the patient in a direction towards the hard palate.

The device was glided downwards and backwards along the hard palate with a continuous but gentle push until a definitive resistance was felt. After connecting the circuit to the IGEL, adequate placement of the device was confirmed with chest wall expansions, square wave capnography and no oropharyngeal leak. If there was early resistance during insertion, the following manoeuvres were tried: (a) Jaw thrust,
(b) Insertion with deep rotation, and (c) Triple manoeuvre.

An appropriate size conventional PVC endotracheal tube was lubricated and inserted through IGEL with the endotracheal tube inserted backward, such that the concave bend was facing down. When the endotracheal tube was advanced smoothly with no resistance, the endotracheal tube cuff was inflated and ventilation confirmed by capnograph.

Smooth advancement of the endotracheal tube without any resistance and a positive capnographic tracing depicts a successful intubation attempt.

The 15mm endotracheal tube adaptor was removed. The I-GEL was removed after stabilising the tube using a stabilizing rod and by grasping the endotracheal tube with the fingers.

After attaching the adaptor to the endotracheal tube, the ventilation was resumed, and the endotracheal tube position was reconfirmed by bilateral equal and adequate rise in chest wall, equal and adequate air entry by auscultation, a capnographic tracing showing square wave.

A "failed intubation attempt" was considered when tactile resistance was felt while advancing the tracheal tube or esophageal intubation.

The second attempt was made with the reinsertion of either the same or different size IGEL and after optimising ventilation, the tracheal intubation was attempted through the device.

Figure 11: Insertion Technique for I-GEL

Figure 12: Manoeuvre for Insertion of I-GEL

Group B (ILMA)

Patients ere made to lie in supine position with head and neck aligned in neutral position and ILMA was inserted and made to rest in the hypopharynx and the cuff inflated with precalculated volume of air (20 ml in size 3 and 30 ml in size 4). Adequate ventilation was confirmed.

If ventilation is not adequate then Chandy's manoeuvre step -1 is performed by manipulating the ILMA ,in situ. If the ventilation was not achieved in the first attempt, the same ILMA device was either reinserted or change of ILMA size was done during subsequent attempt and optimal ventilation was confirmed.

The point at which the tracheal tube comes out from the epiglottic elevating bar was noted on the endotracheal tube before insertion. An appropriate size conventional PVC endotracheal tube (without 15mm connector) was inserted through ILMA with the endotracheal tube inserted backward, such that the concave bend was facing down.

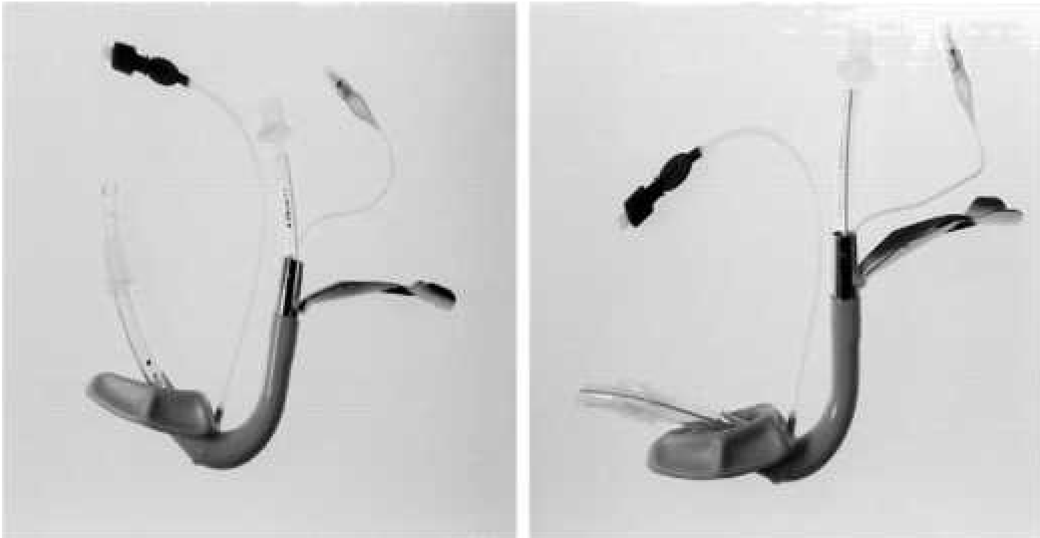


Figure 13: Effect of endotracheal tube curvature on intubation through ILMA

On encountering resistance during passage of the tracheal tube, withdrawal of tracheal tube to one cm beyond the epiglottic elevator bar and "Chandy's manoeuvre step-2" was instituted and advancement of the tube was attempted.

Smooth advancement of the tracheal tube without resistance beyond 15cms and a positive capnographic tracing concludes a successful intubation attempt. The endotracheal tube adaptor was removed. The ILMA was then removed after deflating the cuff and stabilizing the endotracheal tube with the stabilizing rod and grasping the tube with fingers once visible. The endotracheal tube adaptor was reattached and ventilation was reconfirmed by capnography.

A “failed intubation attempt” was considered when (i) tactile resistance was still felt while advancing the tracheal tube despite the adjusting manoeuvres (ii) the tracheal tube was inserted completely without a capnographic tracing (esophageal intubation).

The second attempt was made with the reinsertion of either the same or different size ILMA and after optimising ventilation, the tracheal intubation was attempted through the device.

In both the groups, intubation through the supraglottic airway device was limited to two attempts. Repeated tactile sensation and oesophageal intubation even after two attempts was considered as intubation failure. When intubation was unsuccessful after two attempts, the procedure was dropped and intubation was proceeded with laryngoscopic guidance.

Primary outcome measure was first attempt success rate for blind endotracheal intubation between IGEL and ILMA. Other outcome measures include total time required for tracheal intubation and ease of insertion of supraglottic airway device.

Ease of insertion of the supraglottic airway device would include number of attempts and time required for insertion of the device.

"Supraglottic Airway Device insertion time" was defined as the time from removal of the face mask to the time ventilation was established through the supraglottic airway device with CO_2 confirmation.

"Tracheal intubation time" was defined as the time from loss of CO_2 due to disconnection of the circuit from the supraglottic device to the time of reappearance of the CO_2 from the tracheal tube with no evidence of cuff leak with positive pressure ventilation.

Repeated esophageal intubation or facing tactile resistance even after two attempts was considered as failed intubation or intubation failure. Patients with unsuccessful intubation were excluded from the analysis of total intubation time. Number of failed attempts at intubation was also noted

After achieving tracheal intubation supraglottic airway device is removed. Ease of removal of the device was defined as the time taken to remove the device (time from introduction of the stabilising rod to reconnection of breathing circuit to the tracheal tube). Any catastrophe while removing the device, such as accidental extubation or tube displacement was recorded.

The heart rate and oxygen saturation were recorded continuously and blood pressure was recorded after induction,1 minute and 5 minutes after successful tracheal intubation and then at every 5 minutes till the end of surgery.

Any problem encountered during Complications such as saturation < 95%, intubation, laryngospasm, blood staining trauma), lip or dental injury were looked for intubation was recorded. dental trauma, esophageal of the device (mucosal

OBSERVATION AND RESULTS

Eighty patients of either sex belonging to ASA PS 1 & 2, undergoing elective procedures under general anaesthesia were studied. Analysis of the collected data was done with SPSS Version 15 (SPSS Inc., Chicago, IL).

Demographic data and the time taken for device placement, tracheal intubation and device removal among the groups were analyzed with unpaired t test. Chi-square analysis was used for comparing sex and the number of attempts required for intubation through the supraglottic device insertion.

Chi square analysis with Yates' continuity correction was applied to compare the number of attempts required for supraglottic device insertion and success and failure rate for intubation. Paired t test was used to compare the hemodynamic response at 1minute after intubation from the baseline values within the group. Unpaired t test was used to compare the hemodynamic response to intubation in between the groups. $p < 0.05$ was considered statistically significant.

AGE DISTRIBUTION:

GROUP	N	MEAN (Years)	S.D	p value
I-GEL	40	29.17	5.47	p=0.693
ILMA	40	28.65	6.33	

Table 3: Age distribution of patients in the two groups

The mean age in both the groups was around 29 years. Both groups were comparable with regard to age and there was no statistically significant difference between the two groups. (p=0.693)

WEIGHT DISTRIBUTION:

GROUP	N	MEAN (Kg)	S.D	Student's t- test p value
I-GEL	40	60.82	7.44	t =0.30 p =0.976
ILMA	40	60.77	7.62	

Table 4: Weight Distribution

Both groups were comparable in terms of weight, the average weight being similar - around 60 kg in both groups. In both the groups, majority of the patients were in the range of 61-70 Kg. Six patients in the IGEL and five in the ILMA were in the range of 40-50 Kg.

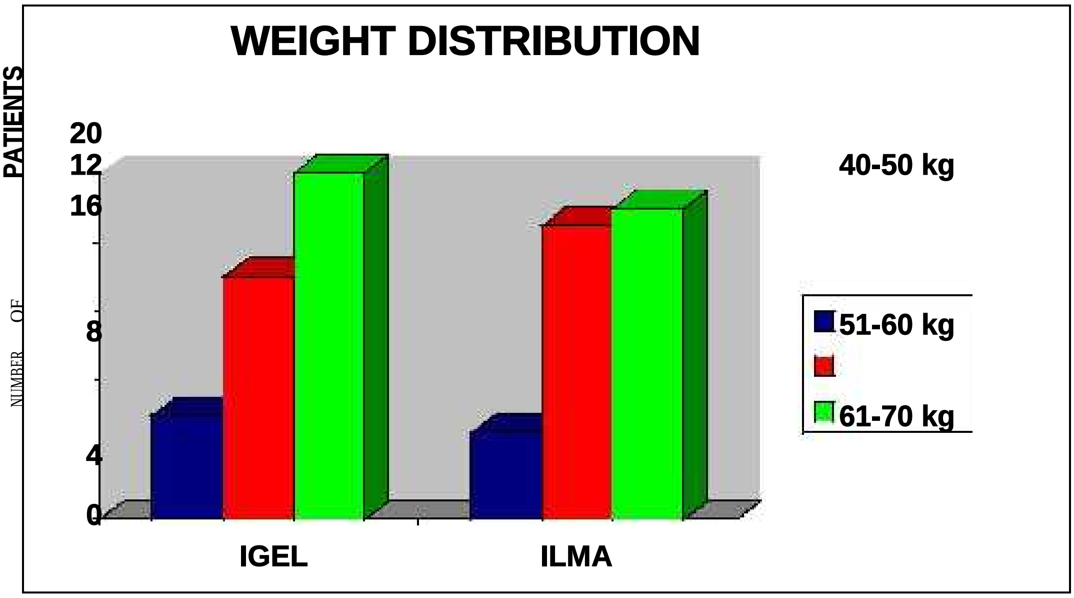


Figure- 14: Weight Distribution

COMPARISON OF SEX DISTRIBUTION

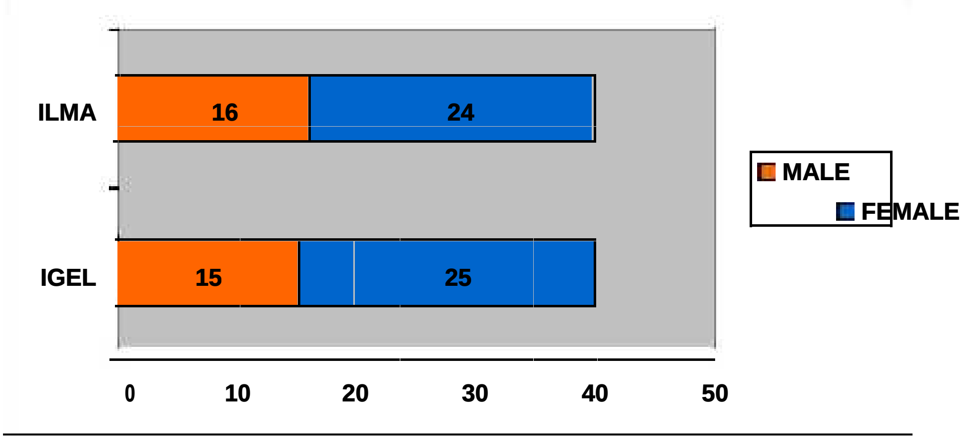


Figure-15: Sex distribution

In ILMA group, 16 were male and 24 were female. In IGEL group, 15 were male and 25 were female. No significant difference was found between the two groups in terms of gender distribution. Chi square analysis: X^2 = 0.53; p=0.818 (not significant).

SUPRAGLOTTIC AIRWAY DEVICE AND ENDOTRACHEAL TUBE SIZE

SIZE		I-GEL	ILMA	TOTAL
Device	**ETT (mm I.D.)**			
3	**6**	12	10	22
4	**7**	28	30	58
TOTAL		40	40	80

Table 5: Supraglottic device and ETT size used in both groups

The size of the supraglottic airway device used in both the groups in the study was 3 and 4. Size 4 was predominately used in both the groups, 30 patients in ILMA group and 28 in I-GEL group. Size 4 was used in patients with weight 50 – 70 Kg in ILMA group and 50-90 kg in IGEL group. In our study, most of the patients' weight was in the range of 50–70 Kg. The size 3 and 4 supraglottic airway devices accommodated 6 mm I.D and 7 mm I.D endotracheal tubes respectively.

SUPRAGLOTTIC DEVICE INSERTION TIME

GROUP	N	MEAN (SECONDS)	SD	P value
I-GEL	40	15.62	2.65	t =2.955 **p =0.004***
ILMA	40	17.17	1.98	

*** Statistically significant**

Table 6: Device insertion time (in seconds) for both groups

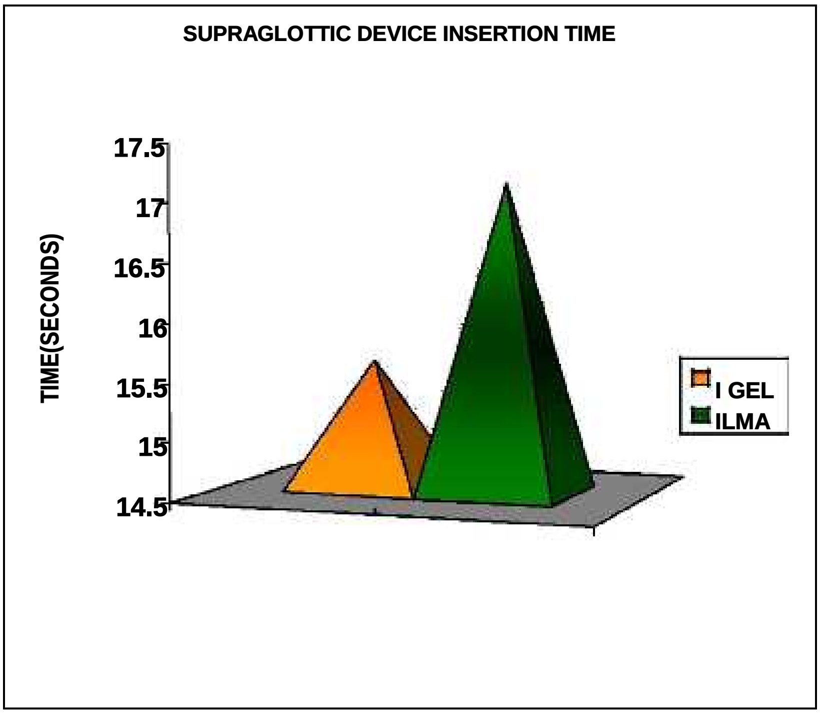


Figure – 16 Supraglottic Device Insertion Time

The least time required for I-GEL placement was 10 seconds in one patient versus 14 seconds in ILMA group. The maximum time required for a single attempt of placement of the device was 18 seconds in I-GEL and 20 seconds in ILMA. The average time taken for the placement of I-GEL (15.62± 2.65 seconds) was significantly less when compared with ILMA (17.17 ±1.98 seconds). ($P<0.05$)

NUMBER OF ATTEMPTS FOR SUPRAGLOTTIC DEVICE INSERTION

GROUP	NO. OF ATTEMPTS		TOTAL	CHI-SQUARE YATES' CORRECTION
	1	2		
IGEL	36	4	40	X^2=0.180 p=0.671
	90%	10%	100%	
ILMA	38	2	40	
	95%	5%	100%	

Table 7: Number of attempts for supraglottic device insertion

Both the devices were placed successfully in the first attempt in 90% of patients in IGEL group and 95% of patients in ILMA group. Insertion and effective ventilation through both devices were possible in all cases in both the groups. In I-GEL group, in three patients, the size 4 device was replaced with size 3. In one patient the same device was repositioned with jaw thrust during second attempt. In patient with body weight in the range of 50 to 60 kg, I-GEL of size 3 and 4, both can be used, so the size selection was at the discretion of the anaesthesiologist.

In ILMA group, during second attempt, two patients required device repositioning and adjusting manoeuvre (Chandy manoeuvre: step 1) to achieve adequate ventilation. There was no significant difference between the two groups in the number of attempts for insertion of supraglottic airway device. (p= 0.671)

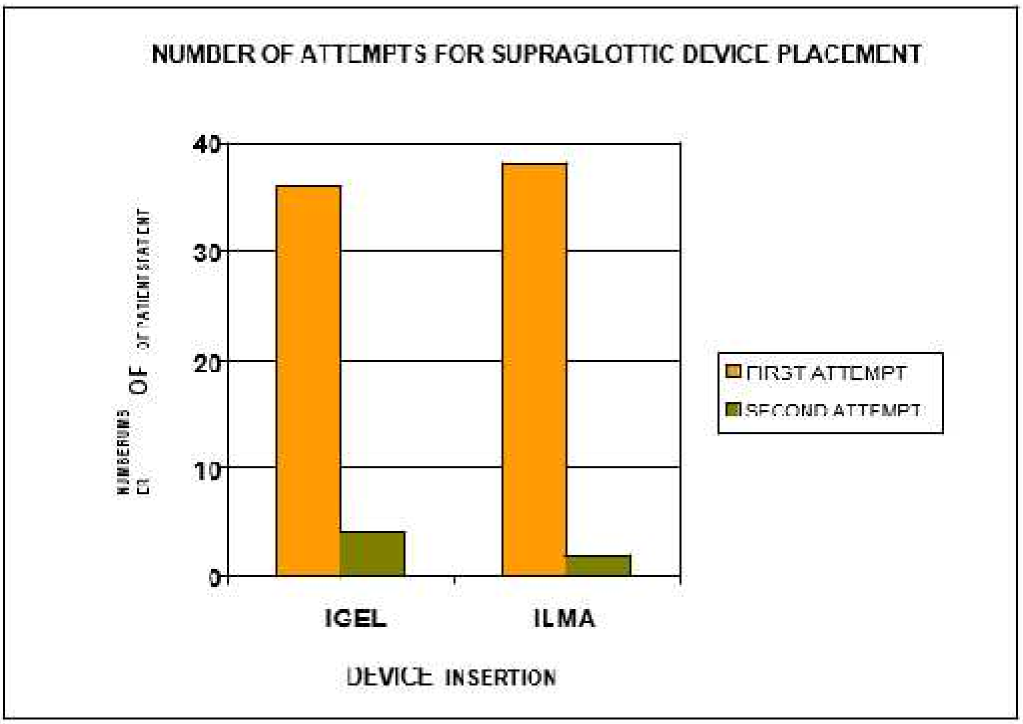


Figure 17: Attempts for supraglottic device placement

TIME FOR FIRST ATTEMPT TRACHEAL INTUBATION

GROUP	N	MEAN (seconds)	SD	Student's t-test p value
I-GEL	24	15.88	2.49	t =0.584 p =0.5611
ILMA	35	16.31	3.04	

Table 8: Time for First attempt Tracheal intubation

The mean time for successful first attempt tracheal intubation was 15.88 seconds and 16.31 seconds in I-GEL and ILMA group respectively. There was no statistical significant difference between the two groups.

NUMBER OF ATTEMPTS FOR SUCCESSFUL TRACHEAL INTUBATION

GROUP	NO.OF ATTEMPTS			TOTAL	CHI-SQUARE YATES' CORRECTION
	1	2	FAILURE		
IGEL	24	5	11	40	X^2=8.78 **p= 0.0124***
	60%	12.5%	27.5%	100%	
ILMA	35	3	2	40	
	87.5%	7.5%	5%	100%	

*** Statistically significant**

Table 9: Number of attempts for successful tracheal intubation

Among 35 patients who were intubated in first attempt, 28 didn't require any manoeuvre and 7 required Chandy manoeuvre step 2 just before intubation.

Three patients were intubated in second attempt in ILMA group despite adequate ventilation achieved through the device during the initial placement. In one patient, resistance to tube was observed at 2cms from the transverse mark, and down-folding of epiglottis might be a reason and hence the same device was reinserted with jaw thrust to prevent epigottic down-folding.

In the other two patients, esophageal intubation occurred in the first attempt and the size 4 was large and replaced with size 3 and both were intubated successfully in second attempt. Despite Chandy manoeuvres and reinsertion of device, repeated esophageal intubation was recorded in 2 patients in the ILMA group who were subsequently intubated successfully under direct laryngoscopy. Both of them had Cormack Lehane laryngeal view 1 under direct laryngoscopy.

Intubation was successful through the I-GEL in first attempt without any manoeuvre in 24 patients and second attempt in 5 patients. In two patients, oesophageal intubation occurred during the first attempt.

During second attempt, the device was removed and reinserted and intubated successfully. In two patients, tactile resistance was felt, and smaller size endotracheal tube was used for subsequent successful intubation. In another patient, size 4 was replaced with size 3 and subsequently intubated.

FIRST ATTEMPT SUCCESS RATE FOR TRACHEAL INTUBATION

First attempt success rate was high in ILMA group with 87.5% while only 60% in I-GEL group. Chi-square test: x^2=7.813; p=0.005. There was a statistical significant difference between the two groups. ($p<0.05$)

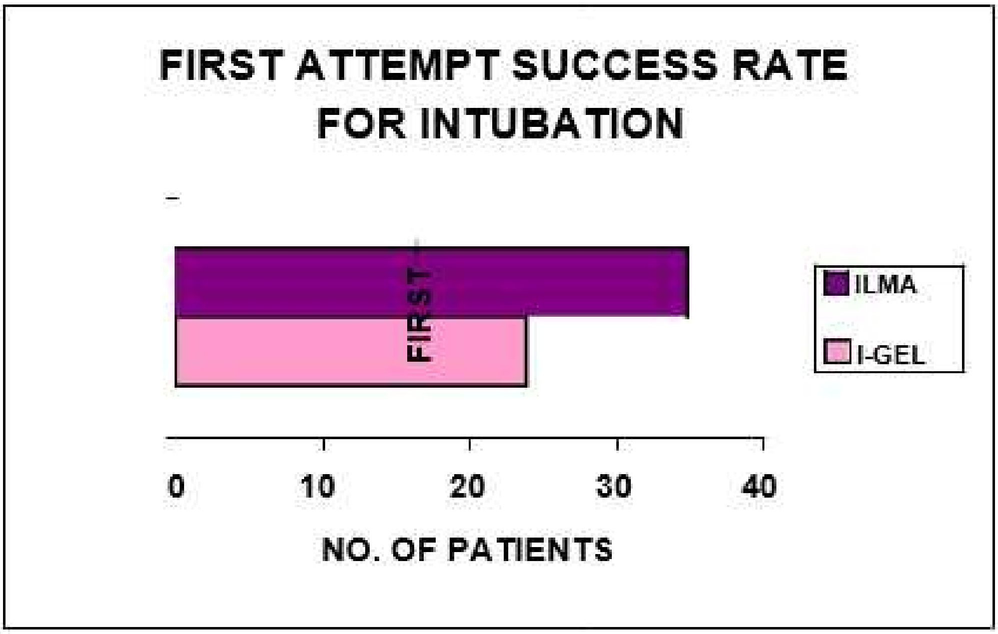


Figure-18: First attempt success rate for tracheal intubation

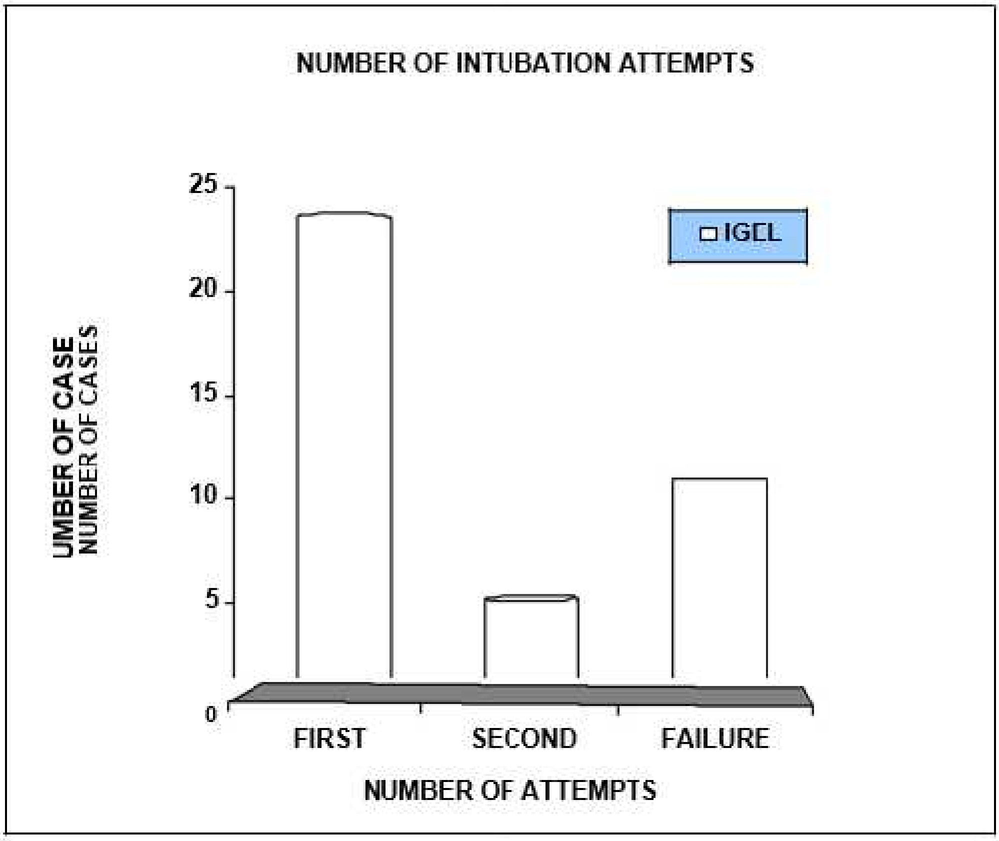


Figure 19: Number of intubation attempts for the I-GEL

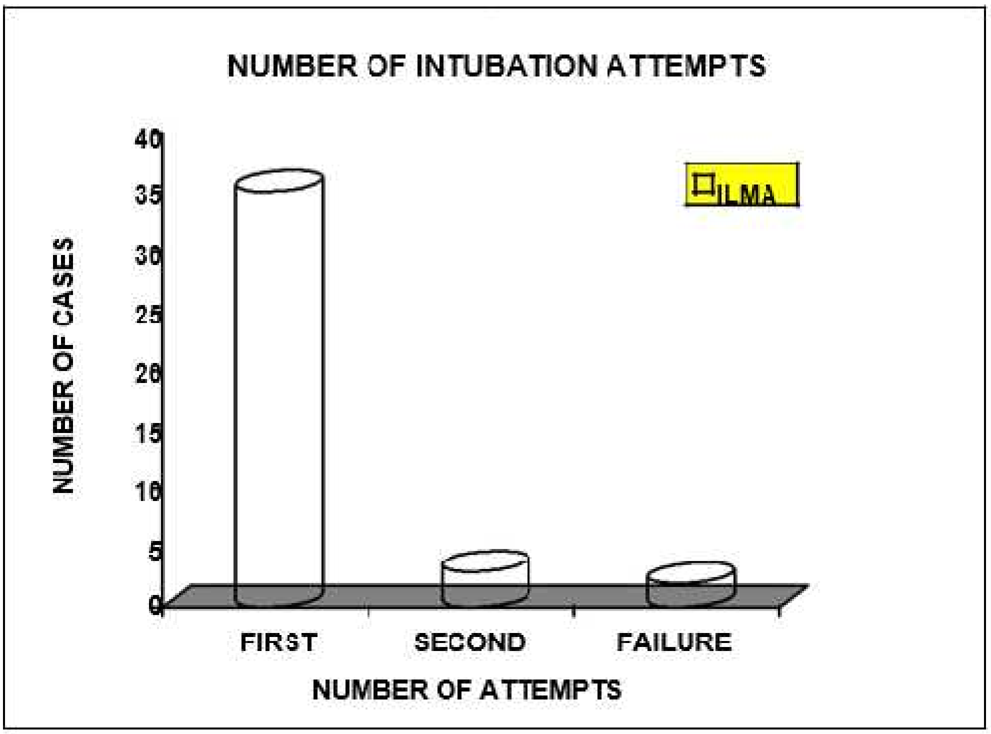


Figure 20: Number of intubation attempts for the ILMA device

SUCCESS AND FAILURE RATE FOR INTUBATION

GROUPS	INTUBATION ATTEMPT		TOTAL
	SUCCESS	FAILURE	
I-GEL	29	11	40
	72.5%	27.5%	100%
ILMA	38	2	40
	95%	5%	100%

Table 10: success and failure rate for intubation

Chi Square test with Yates' correction was applied and x^2=5.878; p=0.0153 (statistically significant)

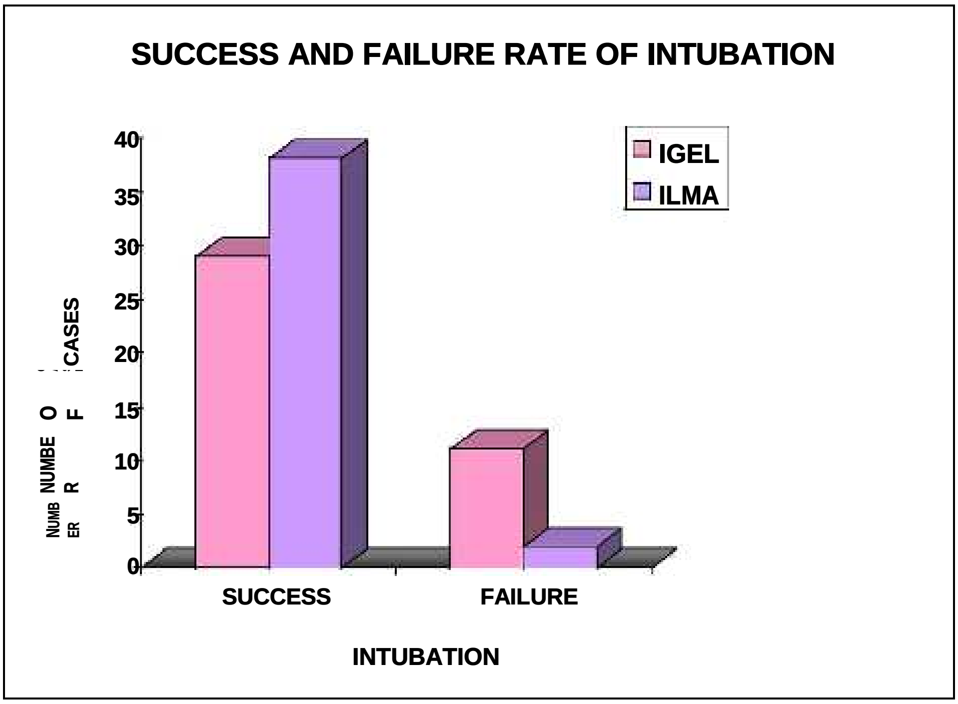


Figure 21: Success and failure rate of intubation for both I-GEL and ILMA

The overall success rate for intubation was significantly higher in ILMA group (95%) than in the I-GEL group(72.5%). We failed to intubate in eleven patients in the I-GEL group and two in the ILMA group. Subsequently they were intubated using direct laryngosopy (macintosh). Those patients who required direct laryngoscopy had a Cormack Lehane grade 1 and 2 laryngeal view and the airway anatomy appeared normal.

SUPRAGLOTTIC DEVICE REMOVAL TIME:

GROUP	N	MEAN (seconds)	S.D	Student's t-test p value
I-GEL	40	15.82	1.61	t=2.079
ILMA	40	16.55	1.50	p=0.041*

*** Statistically significant**

Table 11: Supraglottic device removal time

The average time for I-GEL removal after intubation was significantly less than ILMA ($p<0.05$). There was no incidence of accidental extubation or tube displacement while removing the device.

TOTAL TIME FOR INTUBATION (INCLUDING DEVICE REMOVAL) IN SUCCESSFUL INTUBATION

GROUP	N	MEAN (seconds)	S.D	Student's t-test p value
I-GEL	29	49.69	6.68	t = 0.918
ILMA	38	51.13	6.13	p = 0.3621

Table 12: Total time for tracheal intubation

The mean total time for successful intubation (including the device removal) was 51.13 ± 6.13 seconds for ILMA and 49.69 ± 6.68 seconds for I-GEL. The mean total time would include the time required for supraglottic device insertion, successful tracheal intubation and supraglottic device removal. There was no statistical difference between both the groups in respect to total time required for intubation (including device removal). ($P>0.05$)

COMPLICATIONS:

VARIABLES	I-GEL	ILMA
Saturation <95%	0	0
Dental Trauma	0	0
Oesophageal Intubation	12	4
Laryngospasm	0	0
Mucosal Trauma	6	5

Table-13: Complications during Intubation

The incidence of oesophageal intubation was more with I-GEL in comparison with ILMA. The blood staining of the device was noted and it was an indication of mucosal trauma. Six patients in I-GEL group had mucosal trauma against five patients in ILMA group.

HEMODYNAMIC RESPONSE

The increase in systolic blood pressure, diastolic blood pressure and mean arterial pressure from the baseline values were insignificant ($p>0.05$) at one minute after tracheal intubation in both the groups. When compared among the groups, there was no significant difference in the increase in blood pressure (systolic, diastolic, mean arterial pressure) from the baseline values.

In both the groups, there was a significant ($p<0.05$) increase in heart rate at one minute after intubation from the baseline values. Among the groups, there was no significant difference between the increase in heart rate at 1 min after intubation from the baseline values.

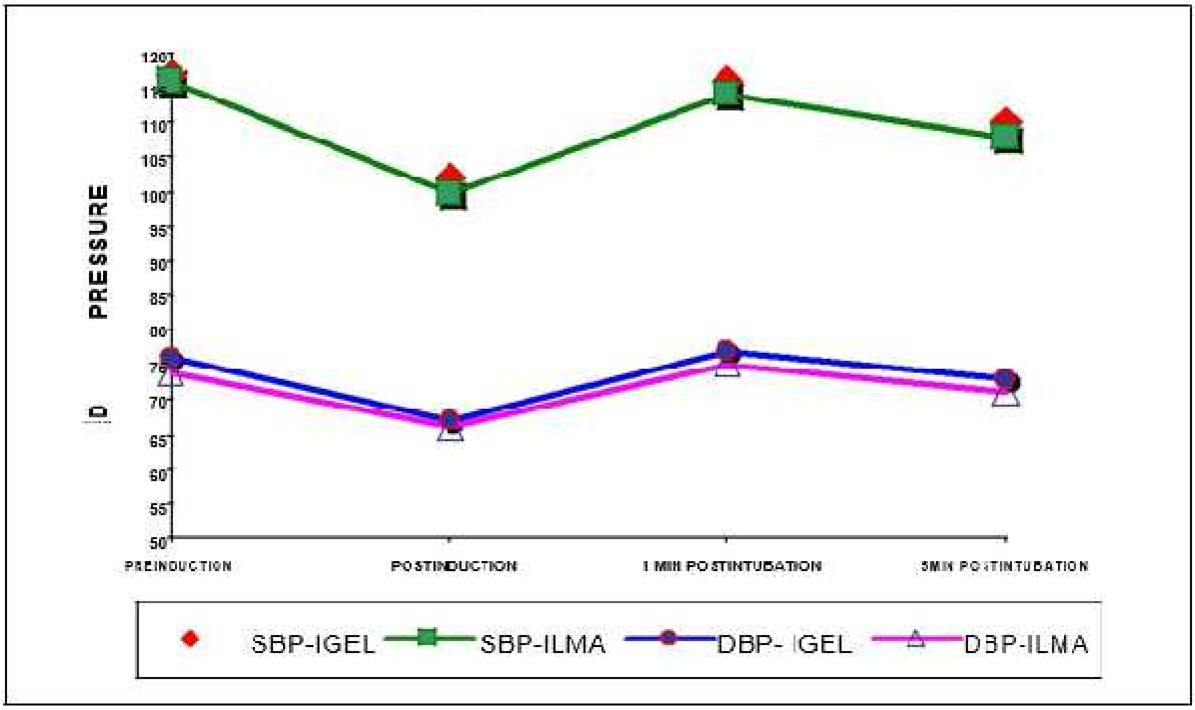


Figure 22: Changes in Systolic & Diastolic blood pressure before & after intubation

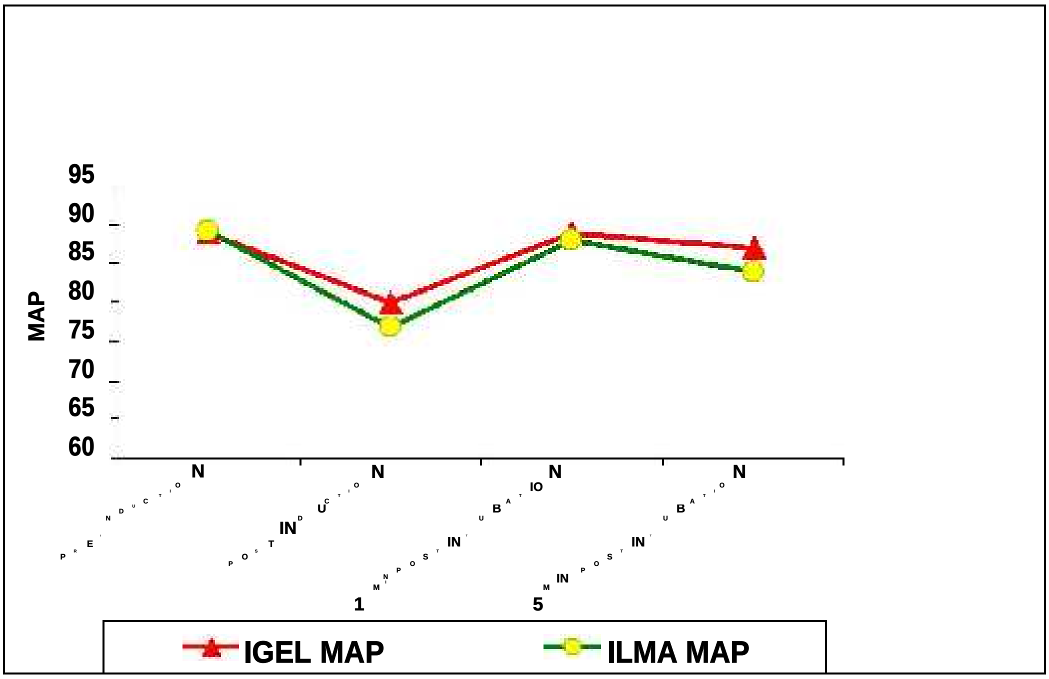


Figure 23: **Changes in Mean Arterial Pressure (MAP) before and after tracheal intubation**

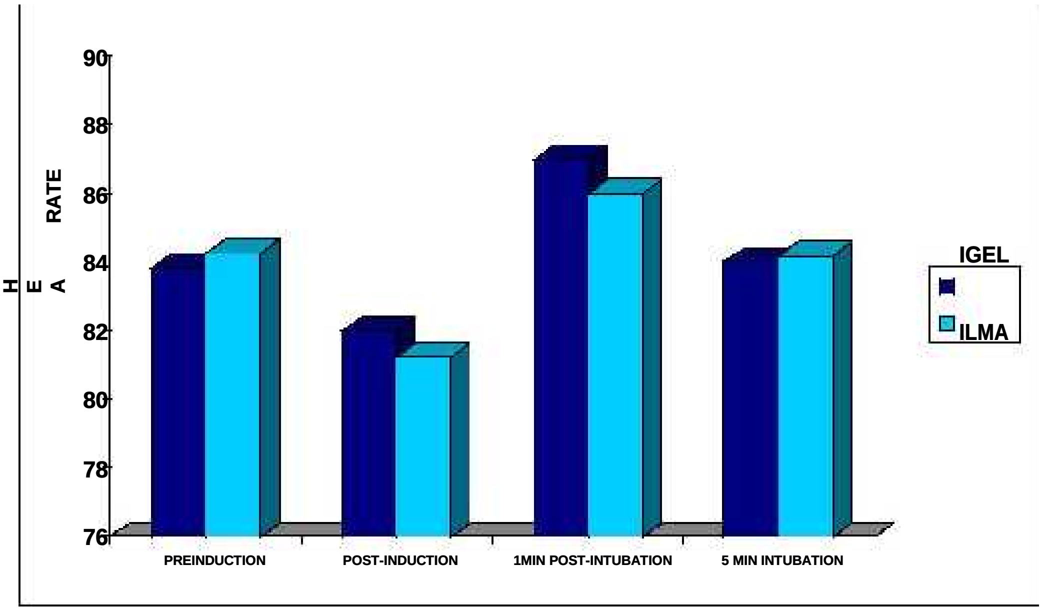


Figure 24: Variation in Heart Rate while using I-GEL and ILMA

DISCUSSION

The mean age, weight and sex ratio were comparable in both the groups. Our study showed that the I-GEL, as a ventilatory device was as effective as ILMA in maintaining the ventilation and oxygenation in the anaesthetized patients with normal airway.

The mean insertion time for supraglottic airway device was significantly less for I-GEL in comparison with ILMA. The I-GEL being an uncuffed peri-laryngeal sealer, the insertion was easy and quick. It also provided a reliable airway.

Both IGEL and ILMA were successfully inserted in all patients. The overall success rate for supraglottic airway device insertion was similar in both the groups. The result obtained with IGEL was comparable with that obtained by Gatward.J.et.al.[29] The device was inserted in first attempt in 36 patients in IGEL and 38 patients in ILMA with no significant difference.

Choosing the size of supraglottic airway device was more important as inappropriate sizing could lead to significant reduction in first attempt success rate for insertion of the device. The size of the supraglottic airway device predominantly used in the study was 4, as majority of the patients' weight were in the range of 50- 70 kg. There were no adverse airway events recorded during placement of the supraglottic airway device.

The overall success rate of blind endotracheal intubation through ILMA with conventional PVC tubes with curvature facing downwards in patients with Mallampatti 1&2 was 95% and was significantly higher than in I-GEL (72.5%). Joo & Rose[9] reported 96.7% overall intubation success rate with reverse orientation of conventional PVC tracheal tubes through ILMA in patients with normal airway.

Kundra et.al.[19] demonstrated a 96% success rate within two intubation attempts with both Rusch PVC tubes oriented in normal direction and with silicone wire-reinforced tubes.

Michalek.et.al.[24] compared the IGEL and ILMA as a conduit for tracheal intubation in manikin and concluded that the success rate for blind tracheal intubation through ILMA was over 80% and IGEL was 63%.

The first-attempt success rate is another important performance indicator for tracheal intubation. The first attempt success rate of blind endotracheal intubation through ILMA was 87.5% similar to that obtained by Joo.et.al [9] and through I-GEL was 60%. The first attempt success rate of blind endotracheal intubation was significantly high in the ILMA.

The curved shape of the ILMA stem which directs the tube anteriorly,[6] and the adjusting Chandy manoeuvre of ILMA used before intubation probably improved the success rate. [16]

An important factor that determines the success rate of tracheal intubation is the angle at which the tracheal tube emerges from the distal aperture of the ILMA[2] and IGEL. Tracheal intubation via an ILMA with the conventional tracheal tube inserted in reverse orientation was first described by Joo and Rose[9]. The reverse orientation of the conventional PVC endotracheal tubes through ILMA reduced the emerging angle of the tube from the ILMA (from 40º to 20º)[9,20,23] and improved the success rate of intubation even though the silicone reinforced tube was not used.

More failure in blind intubation attempts were recorded in I-GEL group. P. Michalek et.al.[24] had observed the same findings in his study. The incidence of the esophageal intubation was common with I-GEL. The reason attributed to this was the relatively straight shape of the

I-GEL stem which has a tendency to direct them posteriorly and thus increase the risk of oesophageal intubation or snaring on the arytenoids.

Joo et.al.[9] had cited that inappropriate positioning of the ILMA in relation to the glottis, as assessed by fibre-optic view, as the reason for an increase in the number of attempts and the incidence of failure to achieve tracheal intubation.

The mean time required for successful tracheal intubation in first attempt was similar in both the groups. Anitha shetty.et.al[27] had obtained similar results with ILMA.

The IGEL has a wider stem. Danha et.al[31] suggested that wider shaft of the channel and absence of bar make the tube passage ‘subjectively easy’.

The time required for the supraglottic device removal after intubation was significantly less in the I-GEL group. This uncuffed device was easier to remove with endo-tracheal tube in situ using a stabilizing rod. Sharma et.al.[13] described difficulties in removing the IGEL after intubation, but we have not noted any significant difficulties by using the silicone stabilising rod from the ILMA set.

The total time required for successful endo-tracheal intubation (including Airway insertion time, intubation time and removal of airway device) was equal in both the groups showing no statistical significant difference. The average total time for successful intubation through ILMA was 51.13 ± 6seconds and for I-GEL was 49.69 ± 6 seconds. Joo et.al[9] had similar total intubation time (from induction to tracheal intubation with exclusion of device removal) with 53.5s for blind endotracheal intubation.

The heart rate response to intubation at one and five minutes was significantly high when compared with the pre-intubation values within the group. Among the groups, the heart rate response to intubation is significantly high in the I-GEL group.

The blood pressure response to intubation recorded at one minute after intubation was insignificant when compared with the baseline values within the group. Among the groups, there was no significant difference in the blood pressure response to intubation at 1 minute after intubation from the baseline values. There was significant increase in the heart rate recorded at one minute after intubation in both the groups but when compared between the groups, there was not much of statistical significance.

There was no incidence of oxygen de-saturation in both the groups. This study had showed that both the I-GEL and ILMA effectively maintain ventilation and oxygenation. Incidence of mucosal trauma (blood staining of the device) and oesophageal intubation were more with IGEL in comparison with ILMA. There was no incidence of laryngospasm or dental trauma in both the group.

SUMMARY

Insertion of supraglottic airway and tracheal intubation through it may be indicated where conventional laryngoscopy fails. The ILMA was specially designed for this purpose. IGEL, a relatively new device has some benefits: disposable, cheap & its wide bore facilitate direct passage of a standard size tracheal tube. It can be a useful adjunct to tracheal intubation in patients with difficult airway as documented in several case reports.[13, 14]

A prospective randomized single blind study was designed to compare the supraglottic airway devices I-GEL and ILMA as a conduit for blind endotracheal intubation in patients undergoing elective surgery under general anaesthesia

After obtaining the Institutional Ethical committee approval, eighty adult patients of ASA Physical status 1& 2 of either sex undergoing elective surgical procedures under general anaesthesia were randomly allocated into two groups, Group A: IGEL(n=40) and Group B: ILMA (n=40). Ease of tracheal intubation was assessed by the first attempt success rate, the total time required for the intubation. Ease of supraglottic device insertion was also assessed by the number of attempts and the time required for the device placement. Any complication during intubation was noted.

The study showed no significant difference between the two groups based on the demographic variables. The mean insertion time for I-GEL was significantly less than ILMA ($p<0.05$). There was no statistical difference between the two groups in number of attempts required for the placement of the supraglottic airway device.

The overall success rate, as well as the first attempt success rate for blind endotracheal intubation was high in the ILMA and were 95% and 87.5% respectively. The failure rate for blind endotracheal intubation through the supraglottic device was significantly high in the I-GEL (27.5%) with high incidence of esophageal intubation when compared to ILMA ($p<0.05$). The mean time for tracheal intubation was equal in both the groups

The time required for supraglottic device removal was significantly less for I-GEL ($p<0.05$). There was no statistically significant difference in the total time required for successful endo-tracheal intubation (including the time for airway insertion, tracheal intubation, device removal) between both the groups. Complications like oesophageal intubation and mucosal trauma were high with the IGEL.

CONCLUSION

We conclude that, based on the results of our study, I-GEL aids easy and rapid insertion as a supraglottic airway device, but when it is used as a conduit for blind endotracheal intubation, the failure rate is high as there is more incidence of oesophageal intubation. In contrary, ILMA being a gold standard device meant for intubation guide, has a high first attempt success rate for blind endotracheal intubation.

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ஆய்வு ஒப்புதல் படிவம்

அறுவை சிகிச்சைக்காக முழு மயக்கம் கொடுத்து எண்டோட்ரகியல் இண்டுபேஷன் செய்வதற்காக பயன்படும் இரண்டு கருவிகளின் பயன்பாட்டை பற்றிய ஆய்வு:

பெயர் :

வயது :

இனம் :

உள்நோயாளி எண் :

வார்டு :

நோய் :

அறுவை சிகிச்சை :

விளக்கம்:

அறுவை சிகிச்சைக்காக முழு மயக்கம் கொடுக்கும்போது எண்டோட்ரகியல் இண்டுபேஷன் செய்ய ஃபாஸ்டிராக் மற்றும் ஐ-ஜெல் என்னும் இரண்டு கருவிகள் பயன்படுகிறது. அவற்றின் பயன்பாட்டை பற்றியும், அவற்றினால் ஏற்படும் விளைவுகள் அனைத்தும் எனக்கு நன்கு புரிகின்ற வகையில் எனது தாய்மொழியில் தெளிவாக விளக்கி கூறப்பட்டது.

என்னுடைய அடையாளம் எந்த வகையிலும் இந்த ஆராய்ச்சி மூலம் வெளியே தெரியாது என்பதை அறிவேன். இந்த ஆராய்ச்சியில் இருந்து எந்த நேரமும் விலகலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் அறிவேன்.

நான் யாருடைய நிர்பந்தமுமின்றி என சொந்த விருப்பத்தின் பேரில் சுய நினைவுடன் இந்த ஆராய்ச்சியில் பங்கு கொள்ள சம்மதிக்கிறேன்.

நோயாளியின் கையொப்பம்

இடம்:

தேதி:

PROFORMA

Name	:				
Group assigned	:				
Age / Sex	:				
IP No	:				
Diagnosis	:				
Surgery	:				
ASA Status	:				Associated medical illness :
Weight	:				
Airway	:	MPC			
Last Oral intake	:				
Premedication	:				
Shifted to theatre	:				
Monitors –baseline values: HR			:		
		SpO2 :			
		BP	:		
IV access secured	:				
Preoxygenation	: 100% oxygen for 3 min				
Induction	:	Propofol		mg.	
Relaxant	:	Inj Atracurium			mg
SUPRAGLOTTIC DEVICE:					
Size	:				
Insertion time (seconds) :					
Number of attempts	:				

Tracheal Intubation

Endotracheal tube size :

Time (seconds) :

Intubation Attempts

One (Without Maneuver) :

One (With Maneuver) :

Two :

TIME required for the removal of supraglottic device :

Total time required for tracheal intubation :

(including supraglottic device insertion and removal)

COMPLICATIONS	***:***
Saturation <95	:
Dental trauma	:
Esophageal intubation	:
Laryngospasm	:
Mucosal trauma	:

Hemodynamic parameters :

1. Pre induction Blood pressure -
2. Post induction Blood pressure -
3. BP 1 min after intubation-
4. BP 5 min after intubation-

1. Pre Induction Heart Rate –

2 .Post induction Heart Rate-

3. HR 1 min after intubation-

4. HR 5 min after intubation-

KEY TO MASTER CHART

IP NO	:	In- patient number
PS	:	**American society of Anaesthesiologist**
		Physical Status
Wt Kg	:	Weight in kilograms
MPC	:	Mallampatti Classification
ETT	:	Endotracheal tube
SBP	:	Systolic Blood pressure
DBP	:	Diastolic blood pressure
MAP	:	Mean arterial pressure
Pre- Ind	:	Pre-induction
Post- Ind	:	Post-induction

GROUP B - ILMA

		PREINDUCTION BP			POST INDUCTION BP			1 MIN AFTER INTUBATION			5 MIN AFTER INTUBATION			HEART RATE			
Sl.NO.	NAME	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	PRE-IND	POST-IND	1 MIN	5 MIN
1	GANESAN	110	80	90	96	70	79	120	76	91	120	80	93	86	80	88	88
2	SARA	110	80	90	96	66	76	110	74	86	108	76	87	88	82	88	86
3	SATHYA	126	76	93	110	70	83	120	80	93	118	70	86	86	84	88	88
4	SAVITHRI	116	86	96	102	62	75	110	76	87	108	72	84	87	88	89	89
5	AGILAN	126	70	89	100	60	73	116	70	85	114	60	78	90	84	89	92
6	BABITA	118	70	86	110	60	77	110	70	83	110	68	82	90	86	88	84
7	AMYRO	120	80	93	96	66	76	116	76	89	106	70	82	88	84	89	88
8	AVIKA	120	80	93	90	66	74	116	74	88	110	68	82	80	70	78	82
9	GOVIND	116	80	92	98	64	75	120	76	91	112	72	85	88	80	88	86
10	MANISHA	126	80	95	106	70	82	118	76	90	116	70	85	80	76	84	82
11	LAKSHMAN	128	80	96	106	70	82	116	78	91	110	72	85	80	76	84	82
12	RAMANA	106	70	82	90	60	70	110	66	81	100	70	80	80	74	83	80
13	RANGIA	116	80	92	100	70	80	118	76	90	112	70	84	86	80	87	88
14	RADHIRA	116	70	85	96	70	79	114	76	89	112	70	84	84	80	85	86
15	RANJAN	118	74	89	96	66	76	118	76	90	110	70	83	80	76	86	86
16	CHINTHYA	120	80	93	100	70	80	110	76	87	116	74	88	86	84	88	86
17	UMA NATH	118	70	86	100	70	80	120	76	91	110	74	86	86	78	86	84
18	SHANTHANU	122	76	91	98	70	79	116	76	89	108	66	80	86	80	88	84
19	MOHINI	126	80	95	100	76	84	110	82	91	112	70	84	84	78	85	82
20	ARULAN	106	68	81	94	60	71	110	68	82	106	66	79	84	76	82	80
21	SAVEENA	126	80	95	100	70	80	116	80	92	114	80	91	89	84	88	88
22	DHANARAJ	120	78	92	100	70	80	116	80	92	110	76	87	90	86	88	84
23	PRITHAM	110	70	83	96	62	73	110	72	85	106	70	82	86	87	89	88
24	RATHI	116	70	85	100	74	83	118	78	91	112	76	88	86	88	90	87
25	SELVIN	117	70	86	98	68	78	116	70	85	112	68	83	84	87	86	86
26	RUKMITHA	116	68	84	96	69	78	110	72	85	118	76	90	79	82	85	82
27	ESWARAN	110	76	87	96	67	77	110	78	89	106	72	83	72	76	78	75
28	JANANI	120	80	93	106	72	83	116	80	92	114	76	89	86	84	89	88
29	ARVINDHA	116	70	85	100	60	73	118	76	90	112	70	84	80	72	79	76
30	SANTRA	112	70	84	96	68	77	110	76	87	108	72	84	82	80	88	86
31	GANPATH	126	76	93	106	70	82	116	76	89	112	70	84	84	86	88	82
32	SARANYA	116	80	92	98	66	77	118	76	90	108	70	83	86	80	86	82
33	SHANTHILEELA	110	76	87	96	68	77	110	72	85	104	80	88	90	82	92	88
34	ASHOK AN	120	74	89	98	68	78	118	70	86	114	76	89	87	88	90	82
35	KALA	120	76	91	104	76	85	126	80	95	120	88	99	78	80	84	84
36	MARIMUTHU	105	74	84	95	60	72	110	76	87	106	72	83	87	89	88	84
37	SHANTINI	100	70	80	94	66	75	106	76	86	104	67	79	74	79	82	80
38	RUKUMANI	120	80	93	90	70	77	126	84	98	110	70	83	94	86	90	89
39	BAGYA	118	70	86	100	66	77	120	76	91	110	70	83	84	80	88	84
40	SENTHIL KUMAR	108	76	87	97	64	75	110	70	83	107	70	82	74	78	82	79

GROUP A - IGEL

		PREINDUCTION BP			POST INDUCTION BP			1 MIN AFTER INTUBATION			5 MIN AFTER INTUBATION			HEART RATE			
Sl.NO.	NAME	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	SBP	DBP	MAP	PRE-IND	POST-IND	1 MIN	5 MIN
1	AMIRTHA	120	84	96	106	70	82	120	80	93	124	80	95	80	76	86	84
2	KANAGARADHA	116	76	89	98	68	78	110	80	90	100	70	80	86	88	89	94
3	DEVIKA	118	82	94	100	66	77	116	80	92	110	70	83	80	82	88	88
4	LAKSHMAN	118	78	91	98	68	78	116	80	92	114	72	86	87	88	90	88
5	KADHIRAVAN	110	70	83	96	66	76	106	70	82	110	76	87	84	86	88	86
6	JEMINA	120	78	92	110	68	82	124	76	92	118	70	86	87	89	90	88
7	MUMTAJ	116	80	92	108	68	81	128	86	100	120	80	93	84	86	89	82
8	SWAPNA	120	82	95	100	70	80	120	80	93	122	80	94	82	84	84	88
9	RUKUMANI	120	86	97	108	70	83	120	80	93	118	80	93	80	74	82	80
10	BABINA	106	72	83	90	60	70	108	70	83	104	70	81	76	78	80	78
11	SUGANTHA	124	76	92	104	70	81	120	80	93	126	66	86	84	82	86	84
12	MANIRAJ	112	70	84	98	68	78	116	74	88	110	70	83	88	86	90	88
13	BANU	116	76	89	100	70	80	120	80	93	122	76	91	80	82	84	84
14	VIJITHA	118	78	91	96	70	79	110	80	90	112	82	92	89	90	92	88
15	RAAGA	116	80	92	98	60	73	118	70	86	116	72	87	88	84	88	86
16	LAKSHITHA	120	78	92	100	70	80	120	80	93	118	70	86	88	86	89	90
17	RAJASYA	114	76	89	110	72	85	117	80	92	120	80	93	88	90	91	90
18	RAJALAKSHMI	124	76	92	100	70	80	120	84	96	116	70	85	84	83	89	90
19	DANIE	118	78	91	98	60	73	110	70	83	112	72	85	86	84	87	90
20	VINOTHA	120	76	91	98	68	78	116	70	85	118	70	86	81	85	88	94
21	SANDHYA	116	68	84	99	66	77	112	68	83	118	74	89	80	80	87	90
22	MANIKANDAN	116	68	84	90	60	70	110	70	83	114	68	83	82	86	87	90
23	VISHNU	118	70	86	97	67	77	114	67	83	116	76	89	82	88	89	86
24	CHINNATHAAI	114	74	87	96	70	79	126	86	99	120	68	85	86	84	85	88
25	PANDYARAJ	108	68	81	90	60	70	110	70	83	106	70	82	86	84	88	87
26	POORNIMA	108	70	83	98	68	78	116	80	92	106	70	82	81	78	85	85
27	ANANYA	114	76	89	98	66	77	106	78	87	124	80	95	82	84	86	82
28	ANITHA	120	76	91	100	60	73	116	70	85	124	72	89	86	84	88	94
29	CHITHRA	121	78	92	110	70	83	120	76	91	116	74	88	76	75	80	84
30	MANIKANDAN	118	70	86	100	70	80	120	80	93	114	72	86	84	82	88	86
31	SANJAY	130	89	103	100	66	77	118	76	90	126	78	94	80	84	96	94
32	NALAYINI	120	76	91	98	66	77	110	70	83	118	70	86	86	87	89	84
33	SHANKAR	116	70	85	120	76	91	108	70	83	112	72	85	86	88	90	86
34	MUNIYAMMAL	128	76	93	116	70	85	126	80	95	124	70	88	84	84	88	86
35	PARAMAN	126	90	102	110	70	83	120	80	93	128	96	107	90	89	106	99
36	PUJITHA	128	86	100	100	60	73	118	70	86	120	76	91	84	86	98	92
37	PRASADKUMAR	122	86	98	106	70	82	124	86	99	118	76	90	84	86	92	88
38	RAJESWARI	120	76	91	100	70	80	118	68	85	116	68	84	84	86	94	92
39	PANKAJAM	128	86	100	100	76	84	124	84	97	126	74	91	82	78	98	91
40	KASTURI	124	76	92	96	68	77	108	70	83	118	76	90	86	84	88	82